'Bovine Spongiform Encephalopathy, the definition of risk, and the (in)applicability of the precautionary principle: assessing the ability of precaution to mitigate the impact of hazardous activities.'

> Elen R. Stokes December 2005

Cardiff University, Law School ESRC-funded Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) UMI Number: U585545

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Introduction

i

"Wisdom is to know, that you do not know." Socrates

Preface

"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing costeffective measures to prevent environmental degradation." Principle 15 of the Declaration of the United Nations Conference on Environment and Development, Rio de Janeiro, 1992.

The words 'precaution' and 'principle' hold far less meaning than the tool that fuses both concepts as the precautionary principle. On the face of it, the precautionary principle can be seen as a manifestation of the sentiment that we should behave in a morallyresponsibly manner, and, with environmental protection at its focus, it encourages anticipatory conduct in response to scientifically-plausible hazards. Essentially, it is adverse to a wait-and-see strategy in relation to health and environmental risk, and its intuitive appeal lies in its widely accepted philosophy that erring on the side of safety is socially desirable. Yet, whilst the underlying message of prudence is a seemingly obvious and simple approach to the future, it has been subject to fierce debate amongst academic circles. For the most part, disputes have centred on the meaning and scope of the precautionary principle, aiming to clarify the nature and extent of precautionary action and determine the hazards to which the principle might apply. It is interesting, and telling, that some two decades after the emergence of the precautionary principle, questions relating to its precise intent, interpretation and implication remain unresolved. In spite of the fact that the notion of precaution is a universally-intrinsic element of human perception of the unknown, the task of translating notions of prudence and caution into a workable instrument of law and policy has presented enormous challenges. Consequently, there is a rich and extensive literature attempting to determine what 'precautionary action' entails.

This thesis departs from the bulk of precautionary-literature by focusing primarily on the threshold of evidence required before the principle is invoked. Whilst it is mindful of the indeterminacy of other aspects of the precautionary principle, such as the operation of cost-benefit analysis provisos, and the distinction between precaution and prevention, the originality of this work lies in its investigation of the point at which we enter into

precautionary territory. It presents the precautionary principle in the light of a distinction traditionally made by the formal discourse of science between risk and uncertainty. In this respect, the precautionary principle is often perceived as a decision algorithm; applying in the face of uncertainty, but not in response to risk. It is frequently cited as a component of the risk analysis process, and to that end it is understood as determining which measures might be adopted in relation to impending hazards.

It is of central importance that, in practice, the application of the precautionary principle is governed by a technical distinction between risk and uncertainty. A critical feature of definitions of the precautionary principle, overlooked by existing literature, is their failure to qualify their use of the term 'uncertainty'. Academic commentators have long recognised the existence of a taxonomy of uncertainty, differentiating between insufficiency, inconclusiveness, contradiction, indeterminacy, ambiguity, and ignorance. Yet, in spite of the distinct categories into which incertitude is arranged, the precautionary principle is deemed to operate in response to 'uncertainty' without qualification as to its specific type and degree. As a result, the operation of precaution rests on a crude division between risk and uncertainty. It is conceivable that this broad distinction is reflective of the inability of scientific risk assessment procedures to acknowledge various levels of incertitude. Indeed, the nature of scientific investigation is such that it focuses on what is known, rather than what is unknown. This is displayed by risk assessment which is essentially a reductionist process through which future hazards are expressed in a single risk estimate. It relies on observations of the past as a means of predicting the occurrence and scale of future hazards that are expected to transpire in a similar manner.

A problem arises, however, when impending hazards bearing little or no resemblance to past incidents emerge. As it stands, risk assessment is incapable of acknowledging that unrecognised risks are still risks; that uncertain risks are still risks; and that denied risks are still risks.¹ Lacking evidence of risk in the past means that similar future hazards may

¹ Cairns Jnr, J. *Editorial:* 'Absence of Certainty is Not Synonymous With Absence of Risk' (1999) 107(2) *Environmental Health Perspectives* 56-58, at page 56.

be, by default, deemed to be safe. The upshot is what is known as a 'false negative error'. Choosing not to act upon a hazard that later proves to be valid is, in effect, antiprecautionary, and renders susceptible the environment or human health to harm and substantial remediation costs.² Yet, the inability of risk assessment to envisage hazards that are not directly comparable to the past rather limits its role in making educated guesses about the future. Scientific discourse has not yet developed the rhetoric with which to express levels of incertitude that exist beyond reference to known *un*knowns. It is unable to articulate human ignorance, contradictory evidence, and ambiguity. Scientific risk assessment, therefore, limits the application of precaution to hazards that present scientifically-plausible threat based on existing evidence of the past.

The inappropriateness of the precautionary principle as a tool for establishing responsibility for the impact of environmental decision-making becomes apparent. This is not simply because it lacks definitional specificity, but also because the tendency for decision-making institutions to frame the future as a known quantity denies the existence of incertitude, creating a conceptual conflict with the aspirations of precaution. Despite claims that it redresses the limits of scientific inquiry, the operation of the precautionary principle is curtailed unless those institutions detach themselves from their deeply embedded deterministic and rational roots. In relation to the precautionary principle, therefore, the application of scientific risk assessment in identifying and calculating the impact of hazards might be described as 'paralysis by analysis'.

² False positive errors on the other hand are, although potentially costly, entirely consistent with the notion of precaution. See Underwood, A. J. and Chapman, M. G. 'Power, Precaution, Type II Error and Sampling Design in Assessment of Environmental Impacts' (2003) 296(1) *Journal of Experimental Marine Biology and Ecology* 49-70, at page 59.

Setting the scene

"The Law is the killy-loo bird of the sciences. The killy-loo, of course, was the bird that insisted on flying backwards because it didn't care where it was going but was mightily interested in where it had been."³

A developed legal system inevitably shapes the nature of risks to which society is exposed, and determines the type of response to those that materialise. To that end, the law, as a means of controlling the production of risk and defining responsibility, is a crucial tool for colonising the future. It is critical to our understanding of what constitutes an undesirable threat and to setting limits to so-called risky activities. Our attitudes to risk very according to what we expect, and the law is fundamental in establishing the expected occurrence and impact of impending hazards and in generating norms of conduct to minimise damage and attribute liability. Traditionally, in the context of environmental protection, the law has adopted either a 'command and control' approach through public law or techniques based on private rights. The notion of command and control envisages a system in which control is centrally held and applied using Government regulations that ascertain the limits of risk-inducing activities. It empowers appropriate authorities to monitor compliance, and imposes criminal and regulatory penalties for non-compliance. A system based on private rights, on the other hand, assigns responsibility to those who own the risk-producing facilities through property or contract law. It relies on the law of torts to enable an injured person to seek compensatory damage or injunctive relief for the impact of a hazard, either by assigning liability to the party owning risk-producing facilities, or to a party bound by contractual terms that rearrange the terms of responsibility for a risky activity.

It is important to note that no legal system reflects a pure vision of either 'command and control' or 'private rights' techniques in risk aversion. Environmental protection is accomplished using a myriad of legal instruments. As a preface to considering the

³ Rodell, F. *Woe Unto You, Lawyers!* (Fred B. Rothman & Co.; Littleton, Colorado; 2nd edition; 1987) chapter 2, at page 20

relationship between the law and the concept of risk, it is useful to consider that the implementation of legal tools in environmental protection is governed by technical, scientific analyses of risk. For example, regulations imposed in accordance with command and control theory might stipulate that chemical emissions must not exceed a specific amount, or that concentrations of pesticides used on crops must remain within certain limits. These levels are invariably scientifically-determined. By the same token, establishing liability under private property or contract law is a matter for the logical underpinnings of scientific enterprise. Locating the source of pollutants, for example, or proving a causative link between source and receptor, depend on scientific threshold of detectability, or the lowest margins of statistical significance. It is essential that, in order to attribute responsibility, the law is dependent on scientifically accurate and objective claims. The law cannot make normative statements without recourse to scientifically certain knowledge. In order to attain legitimacy, legal rules and procedures are inescapably reliant on the authority of scientific expertise. The law is justifiable if it is supported by rational, objective, and certain information deriving from scientific investigation. The acceptance of legal action as legitimate derives from the innate authority of scientific order reflecting tenets that are central to the notion of 'sound science'. Environmental protection using law and policy, therefore, lies on the frontiers of scientific knowledge.⁴

However, the test of scientific endeavour, according to Langmuir, is the 'test of time'.⁵ Modernity has manifested in new strains of environmental hazard, generated by a marked upsurge in technological enterprise. Traditionally, scientific means of predicting the occurrence and magnate of potential hazards were employed using templates of past events to calculate the future. Science is, in essence, a study of regularities. Yet, the novelty with which hazards in the modern era present themselves means that they are incomparable with the past. As such, scientific foresight is incapable of anticipating the future in any meaningful sense. Furthermore, given that the test of scientific endeavour is

⁴ See, for example, McEldowney, J. 'The Environment, Science, and Law' (1998) 1 Current Legal Issues 109-127, at page 109.

⁵ Langmuir, I. 'Pathological Science', Colloquium at The Knolls Research Laboratory, 18 December 1953, transcribed and edited by Hall, R. N., as cited in Huber, P. W. 'Pathological Science in Court', in Burger, E. J. (ed) *Risk* (University of Michigan Press; Michigan; 1993) 97-118, at page 104

the test of time, the impact of scientific and technological advance cannot be known until it materialises. As Langmuir points out that:-

"[e]verybody thought [Pasteur] was a fool – thought there couldn't be any sense to the subject. It took a long time before germs were believed in."⁶

Scientific progress in the modern era is exaggerated, resulting in threats to human health and the environment whose impact is scientifically uncertain until they have transpired. The dependency of legal intervention on scientific evidence, therefore, comes under attack. Although the nature of law in the environmental sphere is contingent on scientific constructions of risk, science is, in fact, unable to articulate the future with the certitude that the law demands. Despite the fact that the formal discourse of science claims to have the capacity to *know* the future through statistical projections, its capacity is seriously undermined by the *unknown* long-term impact of modern hazards, an incomplete knowledge of what is known and what is not known, and the improper application of the past to a dissimilar future.

A destabilised scientific basis has potentially severe consequences for the application of law in the face of environmental threats. The limits of scientific knowledge in predicting the future puts in jeopardy the conventionally-constructed legitimacy of law. It exposes the law to claims that its intervention in the course of hazards is unjustifiable, thus challenging its innate authority and long-standing supremacy in the articulation of the future. It is perhaps surprising, therefore, that, given the flaws in scientific analyses of the future, the law has continued to found itself on scientific prediction as a means of securing formal legitimacy. However, the scientific legitimation of law is not a process that depends on the accuracy with which the future can be foreseen. Instead, legitimation is the product of the formal discourse of science and its central tenets such as rationality, objectivity, and certitude. By relying on the principles of 'sound science', the legal regulation of risk can maintain its assertions of rational, objective, and certain responses to environmental hazards.

⁶ Ibid.

The precautionary principle forces a re-evaluation of the traditional relationship between law and science. Although the law has staked a claim in the precautionary principle, there exist clear tensions between the legal ideals of scientific certitude and the precautionary perspective that the future is, in effect, unknown and incalculable. The impenetrable nature of future hazards makes it difficult, if not impossible, to prescribe the type and level of prudence required by the precautionary principle. The upshot is that definitions and interpretations of precaution vary enormously. The first part of this thesis explores the definitional deficit of the precautionary principle in international, EC and domestic spheres of risk regulation. It charts its emergence in law and policy at each of these levels, and focuses specifically on judicial interpretations of its application. The overriding contention is that a fundamental implication of this definitional deficit is inconsistency in the way the relationship between precaution and scientific risk assessment is perceived.

The second part of this thesis shows continues with this theme, introducing the precautionary principle and scientific assessment in the light of an extensive body of risk literature. It illustrates that, as a result of lacking consensus regarding its meaning and scope, establishing the point at which the precautionary principle applies is an unresolved and contentious issue. Generally, the invocation of the principle is seen as a matter for scientific determination. In practice, risk assessment processes are employed as a means of ascertaining whether an impending hazard can be described as a 'risk' or an 'uncertainty'. This binary distinction between risk and uncertainty is founded on the notion that risks can be calculated using scientific modes of prediction, although uncertainty is innately incalculable because there is a 'data gap'⁷ limiting our understanding of the nature and impact of an expected threat. The risk/uncertainty dichotomy can be described as a difference in the certitude with which they can be expressed. Whereas, according to risk assessment formulae, risk can be articulated with scientific certitude, the notion of uncertainty is used to depict future events whose

⁷ a term used by Professor John S. Applegate in his seminar presentation entitled 'The Chemical Data Gap – Risk, REACH, and Precaution' at the ESRC-funded 'Business, Relations, Sustainability and Society' (BRASS) Centre, Cardiff, 19 May 2005

occurrence and scale cannot be conveyed using precise and definite statistics. The precautionary principle is intended to apply only in anticipation of scientific *uncertainty*.

Yet, despite a longstanding reliance on scientific risk assessment procedures as the principal mechanism through which the future might be comprehended, this thesis submits that the cardinal distinction between risk and uncertainty is flawed. The heart of the problem is the outright dependence of definitions of risk on scientific process. By virtue of its utilisation of scientific methods of enquiry, risk assessment reflects assumptions of rationality, objectivity and certitude that are traditionally associated with 'sound science'. Given that it claims to be a manifestation of scientific ideals, risk assessment procedures are understood as producing rational, objective, and certain expressions of the future. The underlying belief is that scientific investigation is an abstract and impartial channel through which reality, or 'the truth', can be exposed. Quantification is considered to be the most rational means of expressing scientific insight, and, as a result of the specificity imparted by numerical characterisations of the future, scientific prediction is seen as providing an objective account of prospective events. Through claims to rationality and objectivity, scientific enterprise is looked upon as presenting *certain* findings - in the sense that they were generated without recourse to individual bias and are only capable of possessing a single meaning.

This thesis illustrates that science is essentially a social process, thus undermining claims made by its formal discourse to rationality, objectivity and certitude. It is shown that subjectivity is an inevitable component of scientific investigation, and that findings are inexorably informed by individual preference and prejudice. Consequently, scientific constructions of reality are meaningful only in the context within which they were generated. Naturally, given that it is founded on scientific process, risk assessment is subject to similar criticism. Despite the fact that risk assessment professes to craft objective and certain articulations of future hazards, this thesis demonstrates that risk is, in effect, a socially-constructed concept whose existence is governed by subjective perception. With particular reference to sociological theories of risk, it is shown that scientific risk assessment is described as an inappropriate tool for predicting the unknown

and that risk is an incalculable phenomenon. Both Ulrich Beck and Anthony Giddens see the emergence of uncontrollable and unpredictable risk as marking the onset of modernity. Achieving an objectively certain calculation of risk is curtailed by the limitations of human foresight. The advent of the post-industrial modern phase has accentuated the shortcomings of prediction by giving rise to new dangers born of technological progression. Although conventional models of scientific risk assessment tend to use observations of past events to predict threats that are expected to materialise in a similar manner, the modern era spawns novel risks that have no footing in the past. As a result, the future is an inaccessible entity, and predictions of the unknown are meaningless.

Thus, regardless of the fact that scientific risk assessment processes reflect the assumption that the future will mirror the past, our knowledge of the future is, quite simply, imperfect. At a press briefing in February 2004, Donald Rumsfeld, US Defence Secretary, announced that:-

"[r]eports that say that something hasn't happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns - the ones we don't know we don't know."⁸

Although his statement has become renowned for its poor articulation of the future, it is useful in highlighting the rhetorical difficulties encountered in dealing with events that have not vet materialised. Indeed, it can be said that the modern era can be distinguished by its fixation with putting the future at the service of the present.⁹ As Bernstein's extraordinary historical account illustrates, the mastery of risk has been pivotal in marking the transition from 'the past' to 'modern times'.¹⁰ To that end, the concept of

⁸ Donald Rumsfeld, US News Briefing, 12 February 2004.

⁹ Bernstein, P.L. Against the Gods: The Remarkable Story of Risk (John Wiley & Sons; New York; 1996) at page 1 ¹⁰ ibid.

risk is caught up in measures of time, and the ability to define what might happen in the future using the rhetoric of risk is central to what is commonly referred to as contemporary society.

The focus of this thesis is the dialogue with which we engage with the future. It is widely accepted that the conventional means of engaging with the unknown is through definitions of risk. The overriding argument here is that the rhetoric of risk is exclusive in its approach to the future. In its characterisation of future events as risks, it assigns numerical values to essentially unknown occurrences. By applying an inherently scientific mathematical model to define the future, the rhetoric of risk effectively marginalises uncertainty. Despite the fact that the existence and influence of uncertainty is universal, the rhetoric of risk is not equipped with devices through which to articulate the fact that the unknown cannot be meaningfully quantified or known.

The issue can be reduced to determining the extent to which the past ascertains the future. According to scientific modes of risk assessment, numerical expressions of observations of past events are crucial in establishing the course of the future. From this perspective, the notion of scientific certainty in the past is imperative to the legitimacy of predictions of future risk. Thus, scientific certainty and risk are seen as inescapably intertwined mechanisms for demarcating the future.

This thesis can be described as interdisciplinary in its approach. It introduces the precautionary principle in various contexts: in international, EC, and domestic law and policy; against a backdrop of both scientific and economic constructions of risk; in the light of the technical distinction between risk and uncertainty; with regard to the objective/subjective dichotomy in risk definitions; in relation to theories of modernity; and taking into account the claims of the principles underlying social constructivism. The basic premise is that the definition of 'risk' espoused by scientific domains is conceptually inconsistent with the workings of the precautionary principle, and, for as long as scientific means of risk assessment continue to dominate predictions of the future, the precautionary principle is unworkable as a tool for attributing responsibility for the

latent impacts of decision-making. The inappropriateness of the precautionary principle as a component of scientifically-informed analysis is illustrated in a comprehensive study of the BSE crisis.

The overriding premise is that the conflict between the precautionary principle and scientific risk assessment exists in the way they perceive the future. Whereas, traditionally, risk assessment looks to the past to ascertain the future, the precautionary principle is forward-looking and anticipatory. Furthermore, although scientific prediction is based on what we know, the focus of precaution is what we do *not* know. Although much literature has either overlooked or discounted the discrepancy between scientific and precautionary-thinking, the conflict is fundamental to this thesis.

A BSE case study in Part Three provides an ideal forum upon which this theory is tested. An examination of the institutional handling of the epidemic illustrates that scientific knowledge of the disease was given precedence in predicting its nature and impact, in spite of the fact that epidemiological and pathological information about BSE was obviously inadequate. Moreover, notwithstanding claims made by the Government that it had adopted a precautionary approach to BSE, the legislative response to the disease displayed preventive, rather than precautionary, traits. Rather than acknowledging that BSE posed a potential, although scientifically uncertain, danger to human health, the threat of transmissibility to humans came to be presented as a known risk. Thus, legislation adopted in response to the disease was aimed at specific, scientificallydetermined risks, and can therefore be described as upholding the notion of hazard prevention, as opposed to precaution. As a direct result of its overt reliance on scientific understandings of BSE, legal measures introduced by the Government were *reactive*, not anticipatory. The underlying argument is that the implementation of legislative responses to an impending hazard is necessarily contingent on there being scientific certainty in relation to its existence and magnitude. Accordingly, it can be said that the law mediates uncertainty through scientific discourse. Science, in turn, mediates uncertainty by framing the future as a known quantity.

This creates a conceptual conflict with the aspirations of precaution. Despite claims that it redresses the limits of scientific inquiry, the precautionary principle is essentially unworkable unless decision-making institutions detach themselves from their deeply embedded deterministic and rational roots. The inability of scientific prediction to meaningfully calculate the future, together with the practice of utilisation of scientific risk assessment to determine the application of the precautionary principle, effectively restricts the implication of the precautionary principle. Although it provides an appealing ethos of environmental protection, its ability to curb the consequences of the limits of human foresight is inhibited by the shortfalls of the scientific process upon which it is based. The upshot is that, whilst the precautionary principle might cultivate a broadspectrum philosophy of prudence, its ability to demand caution in the face of uncertainty is curtailed by the reliance of both scientific process and legal regulation on certitude.

Why BSE?

The BSE crisis was chosen as a case study for three principal reasons. First, the episode has achieved a degree of closure, and thus events lend themselves to a historical study confined to a period of approximately ten years. In practical terms, this has inevitably made it possible to limit the study to a preset timescale. Secondly, the setting up of the BSE Inquiry, chaired by Sir Nicolas Phillips, has resulted in the creation of a substantial archive of information examining the factual history of BSE and CJD, documenting the responses taken in the context of the state of knowledge at that time. For research purposes, therefore, access to the BSE Inquiry website its collection of letters, memorandum, minutes of departmental meetings, written witness statements, and transcripts of oral hearings has allowed for an empirical study based on a wide range of existing material. Thirdly, events during the BSE crisis are unique in that they bring together broad themes such as: the relationship between risk analysis and science; the affiliation between science and regulation through the law; the interpretation of scientific findings through different media; and the role of MAFF in controlling epidemics; the

impact of pressure from the agricultural export industry on decision-making; and public perceptions of food safety.

The BSE study aims to bring together findings reached in preceding chapters – principally that the operation of the precautionary principle is thwarted by factors beyond mere definitional deficit. Using two theories – first, the theory of the 'marginalisation of uncertainty', and second the theory of the 'bureaucracy of risk' – the BSE analysis provides a platform upon which the theoretical backdrop to the precautionary principle discussed in Chapters Six to Nine can be seen to materialise. In particular, the following themes identified in Part Two of the thesis hold particular resonance in relation to events leading up to, and following, the identification of BSE in 1986:- (i) the maintenance of the conceptual distinction between risk and uncertainty in formal assessments of the threat of BSE to human health; (ii) the misapplication of the term 'risk' to include unparalleled and scientifically-uncertain hazards; (iii) the reliance of MAFF risk assessment on scientific means of prediction; and (iv) the scientific practice of basing risk assessment on observations of past events, illustrated by an analogy drawn by Government scientists between scrapie and BSE.

Methodology

The *raison d'être* of this thesis lies in the following sentiment: "The precautionary principle is essentially a workable concept". The thinking behind this piece of work began in October 2001 when I embarked upon an LL.B Environmental Law course at the University of Bristol Law Department. It is here that I was introduced to the precautionary principle. I chose to write an essay on the 'justiciability' of precaution – a term coined by Elizabeth Fisher¹¹ – which examined the operation of the principle in the aftermath of the High Court decision in *Duddridge*.¹² Although I was duly critical of the

¹¹ See Fisher, E. 'Is the Precautionary Principle Justiciable?' (2001) 13(3) *Journal of Environmental Law* 315-334.

¹² R v. Secretary of State for Trade and Industry, ex parte Duddridge 7 (1995) Journal of Environmental Law 224.

application of Article 174(2) of the EC Treaty in domestic law, my work reflected the opinion that the precautionary principle was not only a desirable tool but also necessary in response to uncertain hazards. It is from this perspective that I approached my Ph.D studies. Initially, the purpose of my thesis was to illustrate the workability of the precautionary principle. However, during my first year of exploring existing literature and case law, and after thought-provoking discussions with my supervisor, Professor Robert Lee, my outlook changed fundamentally. My first impression of works focusing on the precautionary principle was that they unnecessarily overstated the impact of its lacking definition. Yet, as I became immersed in precautionary principle was simply unavoidable, and inevitably essential to any in-depth study. My attention shifted, therefore, to an exploration of the extent and impact of its ambiguity.

A critical point in my studies was the issuing of the *Pfizer*¹³ judgment by the European Court of First Instance. It was at this stage that questions of definition became overshadowed by deep-seated issues such as the relationship between scientific risk assessment and precaution, and, more broadly, the union between law and science. It was apparent that, despite being a fundamental hindrance to the operation of the precautionary principle, the definitional deficit played only a relatively minor role in undermining its application compared with the inherent conflict between scientific risk assessment and precaution. Stemming from the theory that the formal discourse of science is incompatible with the ideals of precaution, the focus of my thesis duly shifted to proving that the precautionary principle is essentially unworkable if its application is determined solely by scientific means. This hypothesis was subsequently tested in a deductive manner. An examination of risk literature and a comprehensive case study of the BSE episode have been tailored to test the validity of my hypothesis. Whereas analyses of risk literature are largely theoretical in their approach, making reference to a wide range of academic commentaries, the BSE study draws upon empirical evidence provided by the Phillips Inquiry archive to illustrate the emergence of major themes such as the

¹³ Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union.* 11 September 2002. European Court Reports 2002 page 00000, at paragraphs 143-145.

marginalisation of uncertainty and the incompatibility between aspirations of science and precaution.

Reference to documents made available by the Phillips Inquiry is consistent with the following categorisation. All evidence cited can be accessed via the official BSE Inquiry website (www.bseinquiry.gov.uk).

Category	Abbreviation
Year book	'YB'
Written witness statements	'Statement number' Statements numbered 1-638
Transcripts of oral hearings	'Transcript number' Transcripts numbered 1-139
Initial background documents	'IBD'

Part One

The definitional deficit of the precautionary principle

1

Chapter One

The precautionary principle: a rationale for its relativity

<u>1.0</u> Introduction

The precautionary principle is a ubiquitous, but slippery, concept. There is an air of 'charming schizophrenia'¹ about it. On the one hand, it is celebrated as a 'cornerstone',² as 'the fundamental principle'³ of environmental law and policy, at the forefront of the campaign for sustainable development. On the other, it criticized for being a notorious bone of contention, infamously vague and without concrete definition. Despite rapid escalation in its use and recognition, the precautionary principle is commonly regard as "a rather shambolic concept, muddled in policy advice and subject to whims of international diplomacy and the unpredictable public mood over the true cost of sustainable living."⁴ Whilst it is undoubtedly growing in significance, it simultaneously generates increasing confusion and scepticism.

By and large, the precautionary principle is seen as a response to problems encountered in policy formulation in the face of scientific uncertainty.⁵ The underlying assumption is that "the damaging effects of human activities may become irreversible before the scientific community can agree the precise nature or scope of their impact; taking precautionary action can help avoid this."⁶ It can be described as a symptom of modernity. Sociologists such as Ulrich Beck and Anthony Giddens illustrate how characteristics of modern society spawn new models of political discord

¹ Philippopoulos-Mihalopoulos, A. 'The Silence of the Sirens: Environmental Risk and the Precautionary Principle' (1999) 10(2) Law and Critique 175-197, at page 193.

² Bergkamp, L. 'Understanding the Precautionary Principle (Part I)' (2002) 1 *Env. Liability* 18-30, at page 18.

³ Cameron, J. and Abouchar, J. 'The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment' (1991) 14 B.C. Int'l & Comp. L. Rev, 1-27, at page 2.

⁴ O'Riordan, T. and Cameron, J. (eds) Interpreting the Precautionary Principle (Cameron May; London; 1994) at page 12.

⁵ Stallworthy, M. Sustainability, Land Use and Environment: A Legal Analysis (Cavendish; London; 2002) at page 48.

⁶ Holder, J. 'Safe Science? The Precautionary Principle in UK Environmental Law', in Holder, J. *Impact of EC Environmental Law in the UK* (Wiley; Chichester; 1997) at page 123.

in relation to risk and the unknown.⁷ The term 'risk society' has emerged to describe the new notion of a 'non-industrial' society. Crucial to its understanding is a marked increase in suspicion of the reliability of science stemming from deep-seated social malaise.⁸ The precautionary principle is perceived as having developed to counteract a loss of scientific authority. Von Moltke explains that:-

"[s]cience almost *never* provides clear proof of major environmental impacts because the environment is too complex to be comprehensively described in strictly scientific terms. For example, despite widespread acceptance of the firm hypothesis that greenhouse gases are capable of trapping heat exist, science remains almost incapable of answering critical questions concerning actual environmental responses to changes in their concentration in the atmosphere."⁹

Thus, the notion of 'precaution' is an instrument for dealing with scientific uncertainty. Essentially, it is representative of the need to change human behaviour towards the environment that sustains our existence.¹⁰ It requires that decision-makers act in advance of scientific certainty so as to prevent environmental degradation.¹¹ Both in its conceptual core, and in its practical implications, the precautionary principle calls for the anticipation of harmful effects.¹² It reflects the proverb that it is 'better safe than sorry'. As Runciman points out:-

⁹ Von Moltke, K. 'The Relationship between Policy, Science, Technology, Economics and Law', in Freestone, D. and Hey, E. (eds) *The Precautionary Principle in International Law: The Challenge of Implementation* (Kluwer Law International; The Hague; 1996) Chapter 6, at page 98, emphasis added. ¹⁰ Cameron, J. and Wade-Grey, W. *Addressing Uncertainty: Law, Policy and the Development of the*

Precautionary Principle, Centre for Social and Economic Research on the Global Environment (CSERGE) Working Paper GEC 1992-43,

⁷ See Grove-White, R. 'Risk Society, Politics and BSE' in Franklin, J. (ed) *The Politics of Risk Society* (Polity Press; Cambridge; 1998) 50-53; Beck, U. 'Politics of Risk Society' in Franklin, J. (1998) 9-22; and Giddens, A. 'Risk Society: The Context of British Politics', in Franklin, J. (1998) 23-34.

⁸ Roberts, S. 'Future Directions in Green Political Thought – Welcome to Jurassic Park: Science, Marxism and the Domination of Nature in the Lost World', <u>www.psa.ac.uk/cps/1998/roberts.pdf</u>, accessed in June 2003, at page 6.

http://www.uea.ac.uk/env/cserge/pub/wp/gec/gec_1992_43.htm, accessed June 2003, at page 1. ¹¹ See, for example, Tickner, J. 'Precautionary Principle', in 2(4) The Newsletter of the Science and Environmental Health Net, (May 1997).

¹² Stein, P. L. Are Decision-Makers too Cautious with the Precautionary Principle?, paper delivered at the Land and Environment Court of New South Wales Annual Conference, 14-15 Oct 1999, <u>http://www.agd.nsw.gov.au/sc/sc.nsf/pages/Stein_3</u> accessed October 2002.

"of course it is better to be safe than sorry (safe is good, sorry is bad, so it's a bit of a no-brainer). What the precautionary principle states is that if there is a chance you might be sorry, it is better to be sorry but safe."¹³

But, whilst its precise definition and implication remain unclear, it can be said that the precautionary principle challenges the conviction with which scientific evidence is expressed. In the face of scientific uncertainty, no evidence of harm should not necessarily be translated as evidence of no harm.¹⁴ In other words, the precautionary principle is aimed at avoiding situations in which uncertainty becomes a 'roadblock'¹⁵ to effective environmental protection.

The precautionary principle has become a universally recognized concept in environmental protection. An extensive body of literature claims that its roots can be traced to environmental and social policy in West Germany during the 1970s (the concept of 'vorsorgeprinzip'),¹⁶ before becoming adopted in various international law provisions and into the law and policy of other domestic jurisdictions.¹⁷ Its prominence grew during the 1970s and 1980s, and it currently enjoys widespread recognition as an intrinsic part of a number of environmental measures. Its political status has augmented, and it has become globally accepted on the environmental agenda. However, the precautionary principle is neither well defined nor consistent.¹⁸ There lacks a common understanding of its meaning and application. As Adams fittingly points out:-

"What becomes clear ... is that the rhetoric of precaution is invoked without any explication of how it might be operationalized in practice. While the terminology has developed from 'measure' to 'approach' to

¹³ Runciman, D. 'The Precautionary Principle', in 26(7) London Review of Books (April 2004) at page

^{3.} ¹⁴ Fisher. E. 'Precaution, Precaution Everywhere: Developing a 'Common Understanding of the Precautionary Principle in the European Community' (2002) 9(1) Maastricht Journal of European and Comparative Law 7, at page 9; Independent Expert Group on Mobile Phones (IEGMP), Report -Mobile Phones and Health (HMSO; London; 2000) at paragraph 6.16.

¹⁵ Eckley, N. and Selin, H. 'All Talk, Little Action: Precaution and European Chemicals Regulation' (2004) 11(1) Journal of European Public Policy 78-105, at page 80. ¹⁶ Fisher, E. (2002) at page 10.

¹⁷ O'Riordan, T. and Cameron, J. (1994) at page 113.

¹⁸ See, for example, O'Riordan, T. and Jordan, A. 'The Precautionary Principle in Contemporary Environmental Politics' (1995) 4(3) Environmental Values 191-212.

'principle', and while governments and NGOs alike advocate the 'principle', there has been less attention paid to what it means in practice."¹⁹

The scale of its universal recognition makes it impossible to achieve uniformity in application. Inevitably, this results in a wide-ranging spectrum of ideas, understandings, claims and expectations.²⁰ The upshot of this is the creation of a 'multifarious'²¹ principle with abstract meanings that lack in practical and operational direction.

Although its generality can be perceived its strength, the 'definitional deficit' of the precautionary principle creates a major obstacle to its implementation. Some commentators have argued that its inherent ambiguity does not affect its operation,²² although its imprecision is more often presented as a major concern.²³ As Van Den Belt and Gremmen note:-

"The formulation [of the precautionary principle] may sound unexceptional, but neither is it of much help as an effective basis for policy, as long as the meanings of the key-terms 'serious', 'irreversible', 'damage', and 'cost-effective' are not sufficiently specified and it is not decided how much scientific certainty (short of full 'scientific certainty') we need before we may (or should) undertake preventive action."²⁴

This ambiguity paves the way for the contradictory application of the precautionary principle in the same context. According to Runciman, the duality of the precautionary principle was captured by a speech by Tony Blair in his Sedgefield

¹⁹ Adams, M. D. 'The Precautionary Principle and the Rhetoric Behind It' (2002) 5(4) Journal of Risk Research 301-316, at page 305.

²⁰ Dratwa, J. 'Making Decisions and Taking Risks with the Precautionary Principle' (2001) www.essex.ac.uk/ecpr/jointsessions/grenoble/papers/ws12/dratwa.pdf, accessed June 2005, at page 2.
²¹ Ibid.

²² Fisher, E. (2002) at page 17.

²³ Codex Committee on General Principles, 15th Session, Paris, 10-14 April 2000, Document CX/GP 00/3-Add 6.

²⁴ Van Den Belt, H. and Gremmen, B. 'Between Precautionary Principle and 'Sound Science': Distributing the Burdens of Proof' (2002) 15(1) *Journal of Agriculture and Environmental Ethics* 103-122 at page 105.
constituency justifying the 'war against terror' in Iraq.²⁵ On the one hand, Blair claimed that 'this is not a time to err on the side of caution'.²⁶ Yet, in the same speech, he also argued that what mattered was taking precautions against future threats, stating that 'it is monstrously premature to think that the threat has passed. The risk remains in the balance here and abroad.'²⁷ Runciman observes that "this, then, is not a time to err on the side of caution and not a time to err on the side of incaution. Such an argument can be used to justify anything."²⁸ The precautionary principle can be invoked to rationalize both precaution and incaution, thus giving rise to the ability to "dress up choice as necessity and necessity as choice".²⁹ Its innate uncertainty allows for the manipulation of its application in order to achieve a desired end. Naturally, discretion in relation to the operation of precaution impedes the pursuit for a hard and fast definition.

The academic fixation with finding a concrete common understanding, as demonstrated by existing literature on the subject, can be criticised for ignoring the true purpose and nature of the precautionary principle in its practical context. The aspiration of creating a rigid definition is adverse to its basic rationale, aiming to mould it into something it was never intended to be. Arguably, this obsession with definition is an attempt to create a precautionary *rule* which will ultimately conflict with, and undermine the essence of the precautionary *principle*.

Yet, whilst it is true that the scope of its operation is, by virtue of its fluidity, potentially wide-ranging, the argument here is that the inherent relativism of the precautionary principle has a particularly significant practical implication. This emerges from a consideration of the relationship between the precautionary principle and conventional models of risk assessment. As practice suggests, the application of the precautionary principle is determined by the outcome of risk assessment procedures that are used to establish whether or not a risk exists. The precautionary principle is commonly understood as applying in the face of scientific uncertainty, and not risk. Principal 15 of the 1992 Rio Declaration, which is taken as the working

²⁵ 5th March 2004.

²⁶ Runciman, D. (2004) footnote 13.

²⁷ Ibid.

²⁸ *Ibid*.

²⁹ *Ibid.* at page 8.

definition of the precautionary principle, provides that its application is prompted by a 'lack of full scientific certainty'.

This brings to light a crucial distinction that features throughout this thesis between risk and uncertainty. Risk analysis dictates that a future event is *uncertain* if neither its frequency nor scale can be quantified. Conversely, a future event can be described as a *risk* if both elements are quantifiable. This distinction becomes significant when contemplated in the knowledge that conventional models of risk assessment are essentially *scientific* processes, underpinned by tenets emanating from the formal discourse of science – such as objectivity, rationality and certitude – reflecting the notion that the future can be expressed in absolute terms. The application of the precautionary principle, then, is dependent on a distinction between risk, which is scientifically articulated by way of objective, rational, and certain quantification, and uncertainty, which presents a situation in which the future is beyond scientific articulation. Unsurprisingly, given the centrality of scientific discourse, a conceptual conflict emerges between risk assessment as an objective, rational, and certain process and the subjective and the indeterminate operation of the precautionary principle.

The following section illustrates that, as a consequence of its lacking definition, the precautionary principle is an instinctively relative and thus subjective concept. It is proposed that the rationale for this definitional deficit is four-fold. A tiered model illustrates that the failure to provide a universal definition or understanding can be explained with reference to ambiguities both in the precautionary principle's substructure and in the individual components of its definition. The first three tiers demonstrate that the definitional deficit stems from the principle's foundational framework. The first tier represents the ethical basis of environmental law and policy, and seeks to highlight the impact of moral pluralism on the definition of the Reference to both anthropocentric and ecocentric precautionary principle. philosophical stances is useful in illustrating that the meaning and operation of precautionary-thinking are subject to the philosophical ideals underpinning its definition. The second tier considers the very nature of principles per se, highlighting that the 'principle' status of the precautionary principle thwarts any efforts to arrive at a common definition. The third tier recognises the inexorable link between the concept of sustainable development and the precautionary principle, and suggests that

definitional difficulties associated with sustainable development inevitably infiltrate definitions of the precautionary principle. The fourth and final tier shifts focus from its foundational aspects to the precautionary principle itself, examining its internal ambiguity and definitional inconsistency. Contrary to the widespread belief that the precautionary principle derives solely from the German concept of 'vorsorgeprinzip', this section argues that in fact the principle developed independently in a number of different jurisdictions, resulting in a range of varying interpretations. The diversity with which definitions are framed inevitably leads to the argument that the principle is context-dependent and subjective. By examining definitions of the precautionary principle in international, EC, and domestic law and policy, it becomes apparent that conflicting interpretations of precaution make it a highly contentious and litigious concept. Chapters Two to Five provide a detailed consideration of the meaning and status attributed to the precautionary principle at international, EC and domestic levels. The overriding premise is that, whilst the inherent ambiguity of the precautionary principle is often seen as a pretext for developing diverse translations so as to contend with wide-ranging consequences, its relativity generates a discord with the scientific foundations of risk assessment. The impossibility of finding an objective vantage point from which to evaluate its application renders it inconsistent with the rhetoric of 'risk' which derives from scientifically rational, objective, and certain assessment.

Following a detailed examination in Chapters Two and Three of the notion of precaution in international environmental protection, and after illustrating that the precautionary principle is so lacking in normative content that it fails to impose any general obligation in international law, this thesis turns its attention to the operation of precaution in the EC. Chapter Four traces the evolution of the precautionary principle in EC law and policy before analysing patterns in judicial interpretation. In particular, it focuses on nine landmark decisions by the CFI and ECJ as a means of tracing the development of precautionary-jurisprudence. A distinction is made between the judgments of early case law and more recent decisions. Early case law shows that, despite its display of a precautionary approach, the Courts were reluctant to make reference to the precautionary principle. However, a CFI decision in 2002 (*Pfizer*) marked a shift in the judicial response to the notion of precaution, indicating the onset of the new era in precautionary philosophy in the EC. Post-*Pfizer* cases confirm that

not only have the Courts become increasingly willing to explicitly cite the precautionary principle, but they have also sought to develop the operational framework within which the principle rests. A critical aspect of recent judgments is their differing interpretation of the level of scientific uncertainty required to trigger precautionary action. Whereas the CFI in *Pfizer* and *Alpharma* considered that the precautionary principle comes into operation in the face of a scientifically-verified risk, later cases such as *Wadden Sea* confirm that the Courts expect the precautionary principle to precede the scientific ascertainment of risk. These judgments can be seen as evidence of a liberalisation of the threshold of precaution, and, more broadly, recognition of the limits of scientific foresight. This brings to light an interesting dilemma for the precautionary principle. Part Two of this thesis refers to what might be called 'the paradox of precaution', which draws attention to the simultaneous reliance on, and rejection of, the formal discourse of science by the precautionary principle.

For the time being, however, it is enough to draw attention to, and offer explanations for, the definitional deficit of the precautionary principle. This first part of the thesis illustrates that the precautionary principle is not a single established concept, but a name that has come to denote several distinct ideas, each of which claims to be the precautionary principle properly understood. It explains that the definition and implementation of the precautionary principle ultimately hinges on: (i) the way in which environmental ethics are perceived (Chapter One); (ii) the characteristics of principles *per se* (Chapter One); (iii) the interpretation of the concept of sustainable development (Chapter One); and (iv) its inconsistent development in international, EC and UK spheres (Chapters Two to Five).

<u>1.1 Explanations for definitional deficit</u>

• <u>1.1.1 Environmental ethics</u>

In the words of Hughes and Jewell, "there is no one single moral basis on which environmental law rests but rather a number".³⁰ It is possible to identify a wide range of perceptions of what constitute 'the environment', each reflecting different moral concerns. Alder and Wilkinson classify these moral positions into: traditional anthropocentrism; enlightened anthropocentrism; extended anthropocentrism; non-anthropocentric individualism; concern for animal welfare; and ecocentrism.³¹ Broadly speaking, however, this range of ethical perspectives can be divided into two main schools of thought – anthropocentrism and ecocentrism – which sit at polar opposite ends of the 'moral scale'.

For the purposes of its definition, it is important to question whether the precautionary principle is underpinned by any particular ethical position. Alder and Wilkinson suggest that it is devoid of moral inclination, stating that:-

"[t]he precautionary principle does not tell us what we should take precautions against and what must be sacrificed in the process. In other words the precautionary principle is consistent with any of the ethical perspectives."³²

As a result, the precautionary principle may be defined and implemented in a way consistent with any ethical perspective. This argument is reflected in an article written by Weiss, who claims that there are five definable attitudes towards risk that shape the way in which the precautionary principle is understood and applied: (i) scientific absolutism; (ii) technological optimism; (iii) environmental centrism; (iv) cautious environmentalism; and, (v) environmental absolutism.³³ According to the scientific absolutist standpoint, the precautionary principle should only be invoked

³⁰ Hughes, D. et al, Environmental Law (Butterworths; 2002; London) at page 20.

³¹ See Alder, J. and Wilkinson, D. Environmental Law and Ethics (MacMillan; London; 1999) chapter 2.

^{2.} 32 *Ibid.* at page 150.

³³ Weiss, C. 'Scientific Uncertainty and Science-Based Precaution' (2003) 3(2) International Environmental Agreements: Politics, Law and Economics 137-166, at page 144.

when a danger created by a particular action is scientifically proven. The environmental absolutist takes the opposite stance, requiring that potentially hazardous activities are postponed until it is proven that no harm will ensue.

This has major and inevitable implications for attempts to achieve a single definition and application of the precautionary principle, since its interpretation is dependent on the object of moral concern in relation to which precautionary approaches are deemed appropriate.³⁴ The dichotomy, for example, between ecocentric and anthropocentric positions "may seem somewhat esoteric, suitable only for the philosophy class, but it is actually of great practical relevance to the protection of the environment."³⁵ The interpretation of the precautionary principle will depend on the motivating ethical stance. An anthropocentric interpretation of the precautionary principle will differ from an ecocentric one. Thus, as a result of this broad scale of moral positions, understandings of the precautionary principle will vary enormously.

<u>1.1.2 Anthropocentrism</u>

"People have seen themselves as placed, not just at the relative centre of a particular life, but at the absolute, objective centre of everything. The certainty of Man has been pretty steadily conceived, both in the West and in many other traditions, not as an illusion of perspective, imposed on us by our starting-point, but as an objective fact, and indeed an essential fact, about the whole universe."³⁶

Essentially, the anthropocentric ethical position asserts that only humans are valuable in themselves.³⁷ Humans have intrinsic value and moral standing. Conversely, non-human entities have external value and lack moral standing. In the words of

³⁴ Alder, J. and Wilkinson, D. (1999) at page 150.

³⁵ Garner, R. Environmental Politics (Prentice Hall; London; 1996) at page 42.

³⁶ Midgley, M. 'The End of Anthropocentrism?', in Attfield, R. (ed) *Philosophy and the Natural Environment* (Cambridge University Press; Cambridge; 1994), as cited in Gillespie, A. *International Environmental Law Policy and Ethics* (Oxford University Press; Oxford; 1997) at page 4.

³⁷ Pierce, C. and VanDeVeer, D. (eds) *People, Penguins and Plastic Trees* (Wadsworth Publishing Co.; Belmont; 1995) at page 184.

Protagoras, "man is the measure of all things."³⁸ Kant proclaimed that "[m]an ... is the ultimate purpose of creation here on Earth."³⁹ According to Sophocles:-

"[w]onders are many on earth, and the greatest of these is man ... He is master of ageless Earth, to his own bending ... He is lord of all things living; birds of the air, Beasts of the field, all creatures of sea and land."⁴⁰

The anthropocentric paradigm has its roots in early rationalism⁴¹ and the separation of humanity from Nature, as advocated by philosophers such as Pythagoras and Plato.⁴² This understanding developed from two belief systems – first, the belief that the (immortal) soul and the (mortal) body are separate entities, and the idea that the mental being is disconnected from the physical being;⁴³ and secondly, the belief that abstract reason, rather than empirical observation, is the source of all knowledge.⁴⁴

On the basis of the assumption that only humans are intrinsically valuable and rational, the existence of everything outside human identity is questionable.⁴⁵ This argument draws upon the concept of individualism, utilized by Thomas Hobbes in *Leviathan*, in which it is argued that society comprises of nothing more than self-interested atomistic individuals.⁴⁶ The significance of the individual can be further traced in the works of contemporary liberal philosophers – such as, John Rawls,⁴⁷ Ronald Dworkin,⁴⁸ and Robert Nozick.⁴⁹

³⁸ Protagoras, as cited in Rodman, J. 'The Dolphin Papers' (1874) North American Review 12, at page 16.

 ³⁹ Kant, I. Critique of Judgement (MacMillan; London; 1914), as cited in Gillespie, A. (1997) at page 4
 ⁴⁰ Sophocles, translated by Watling, E. F. The Theban Plays (Penguin Books; Harmondsworth; 1947), as cited in Gillespie, A. (1997) at page 4.

⁴¹ Gillespie, A. (1997) at page 4.

⁴² *Ibid*. at page 5.

⁴³ Wheelwright, H. The PreSocratics (The Bobbs-Merrill Co.; Indianapolis; 1960) at page 130; Oelschlaeger, M. The Idea of Wilderness: From Prehistory to the Age of Ecology (Yale University Press, New York 1991) at 57-60; Descartes, R. Discourse on Method; Meditations (Penguin Books Ltd.; London; 1968) at section 4, part 19.

⁴⁴ Cottingham, J. Rationalism (Paladin: London; 1984) at page 18; Hargrove, E. The Foundations of Environmental Ethics (Prentice Hall; New Jersey; 1989) at pages 22-3 and 35-7.

⁴⁵ Descartes, R. *Philosophical Writings* (Routledge; London; 1985) vol. 1.

⁴⁶ Hobbes, T. Leviathan (Penguin; Harmondsworth; 1976) at page 83.

⁴⁷ Rawls, J. A. *A Theory of Justice* (Oxford University Press; Oxford; 1972).

⁴⁸ Dworkin, R. Taking Rights Seriously (Duckworth; London; 1977).

⁴⁹ Nozick, R. Anarchy, State, Utopia (Oxford University Press; Oxford; 1974).

The upshot of this ethical position is that humanity is absolved of culpability for the exploitation of non-human entities. It assumes authorisation to use and abuse the environment as humans see fit.⁵⁰ The environment is seen merely as a means to an end: the end being man.⁵¹ The environment is valuable, but only to the extent that it serves the purposes of the human race. As Marx notes, "[t]he purely natural material in which no human labour is objectivised ... has no value."⁵² From this perspective then, environmental protection can only ever be justified on the ground that it safeguards that which is ascribed value. The intrinsically invaluable environment need not be protected as such.

1.1.3 Changing moral positions and attempts to unify environmental O ethics

Given that the pursuit of self interests does not always coincide with achieving environmental protection,⁵³ anthropocentrism, as an ethical basis for action, does not In response to this concern, necessarily prevent environmental degradation. ecocentrism emerged as an alternative ethical basis, shifting emphasis from the perception of the environment in terms of its benefit to humankind to its perception as an entity worthy of protection in itself, irrespective of its attributed human value. Drawing upon the moral position advocated in the works of Rousseau,⁵⁴ ecocentric arguments contend that human beings are communal animals "whose true nature can be realized only as part of a wider community of mutual support and co-operation."55 In recognition of the anthropocentric and ecocentric extremes, the ultimate challenge, of course, is to "unify all ethics with regard to the environment under a single

⁵⁰ Gillespie, A. (1997) at page 9.

⁵¹ Kant, I. Metaphysics and Morals (The Bobbs-Merril Co.; London; 1973) as cited in Gillespie, A.

⁽¹⁹⁹⁷⁾ at page 13. ⁵² Marx, K. *Capital* (Foreign Publishing; Moscow; 1984) vol. 1 at pages 206-7; and vol. 3 at page 745; see also, Smith, A. An Enquiry Into the Nature and Causes of the Wealth of Nations (Methuen; London; 1904) vol. 1 at pages 32-3.

⁵³ Gillespie, A. (1997) at page 27; see also Panjabi, R. K. L. 'Idealism and Self-Interest in International Law: The Rio Dilemma' (1992) 23 Californian Western International Law Journal 189, at pages 194-

⁵⁴ Rousseau, J. J. translated by France, P. Reveries of the Solitary Walker (Penguin Books; London; 1979); see also Leopold, A. A Sand County Almanac (Oxford University Press; Oxford; 1949) at pages vii-ix and 224-5.

⁵⁵ Alder, J. and Wilkinson, D. (1999) at page 49.

framework capable of answering all questions".⁵⁶ He does, however, concede that this is an 'overly optimistic' goal.⁵⁷ Pluralism in environmental positions is unavoidable. The result is a diverse range of differing ethical positions with fundamentally incompatible objectives, generating wide-ranging interpretations of the precautionary principle, from 'weak' constructions of precaution to 'strong'.

'Weak' interpretations, associated with anthropocentrism of the precautionary principle, propose that the lack of full scientific uncertainty is no justification for preventing an action that might be harmful.⁵⁸ Whilst it accepts that environmental discharges may create some threat which science cannot prove, in effect it only recognises those uncertain facts "beyond science's current eyesight".⁵⁹ Such interpretations are likely to induce some cost-benefit analysis and a trade-off between environmental and commercial interests. 'Strong' interpretations, more commonly associated with ecocentrism, demand the impossible – proof of absolute safety before a potentially harmful activity is permitted.

This divergence is a sign that one's position on the ethical scale inevitably influences one's interpretation of the objectives of the precautionary principle, which will in turn determine the way in which it is defined and applied. In the light of the fact that environmental principles are designed to deal with a lack of moral monism, the precautionary principle must be broadly framed so as to accommodate pluralism in underlying ethical stances. Breadth of definition, however, creates scope for inconsistent interpretations of precaution, thus advancing the argument that the precautionary principle lacks in objective existence.

⁵⁶ Gillespie, A. (1997) at page 135.

⁵⁷ Ibid.

⁵⁸ See for example, Principle 15 of the United Nations Conference on Environment and Development (UNCED) Rio Declaration 1992.

⁵⁹ Hunt, J. 'The Social Construction of Precaution', in O'Riordan, T. and Cameron. J. (eds) (1994) at page 121.

<u>1.2 Environmental principles</u>

"I don't like principles ... I prefer prejudices."⁶⁰

The definitional deficit of the precautionary principle is undoubtedly a symptom of its 'principle' status. Environmental law is a sphere rich in principles, including, for example, the precautionary principle, the principle of sustainable development, the polluter pays principle, and the principles of preventive action and rectification at source. General concepts and principles have been formulated to accommodate divergence in moral positions. In order to encompass differing philosophical stances, there needs to be a degree of flexibility in the way principles can be interpreted.⁶¹ This requisite fluidity, however, inevitably generates problems in relation to the certainty and precision with which principles are framed.

Principles, according to Dworkin are "the whole set of … standards other than rules."⁶² The distinction between legal rules and principles is a logical one.⁶³ Whereas a rule possesses an 'all-or-nothing' characteristic, stipulating specific conduct, a principle "states a reason that argues in one direction, but does not necessitate a particular decision."⁶⁴ Principles, by definition, are not intended to specify particular objectives or rules of behaviour. Rather, they are general guides to action,⁶⁵ indicating certain *types* of response, and it is "unprofitable to examine either legal or policy principles for concrete solutions to particular problems."⁶⁶ Whilst principles might point in favour of a particular result, they do not stipulate a specific outcome.⁶⁷ Fisher notes that "while the concept of 'principle' will vary depending on its jurisprudential and jurisdictional context, in all cases a principle is not an

⁶⁰ Wilde, O. An Ideal Husband (Nick Hern Books; London; 1999) Act IV.

⁶¹ Bell, S. and McGillivray, D. Environmental Law (Blackstone Press; London; 5th edition; 2000) at page 39.
⁶² Dworkin, R. M., 'Is Law & System of Bule-2' in Drubin D. M. (1997).

⁶² Dworkin, R. M,. 'Is Law a System of Rules?', in Dworkin, R. M. (ed) *The Philosophy of Law* (Oxford University Press; Oxford; 1977) at page 43.

⁶³ *Ibid.* at page 45.

⁶⁴ *Ibid.* at page 47.

⁶⁵ Alder, J. and Wilkinson, D. (1999) at page 149.

⁶⁶ *Ibid.* at page 148.

⁶⁷ Hart, H. L. A. The Concept of Law (Clarendon Press; London; 2004) at page 261, see also, Stone, C.

D 'Is There a Precautionary Principle?' (2001) 31(7) Environmental Law Reporter 10790.

'explicitly formulated' rule that is unchanging in its application."⁶⁸ Instead, its application is flexible and context-dependent.⁶⁹ It is contingent first, on the particular circumstances of a case, and second, on the relationship between the precautionary principle and other principles of environmental law and policy.⁷⁰ By virtue of its inherent fluidity, the precautionary principle can be described as a heterogeneous concept.⁷¹

Some commentators claim that its ambiguous and contextually-dependent nature is immaterial to its practical significance. Cameron, for example, argues that the precautionary principle "is not intended to be a command and control-type regulatory standard and this does not in any way deny its general effect as a general principle."72 Boyle also claims that its practical viability derives from its ability to "lay down parameters which affect the way courts decide cases or the way an international institution exercises discretionary powers"⁷³ and to "set limits, or provide guidance, or determine how conflicts between other rules or principles will be resolved."⁷⁴ Yet, this argument neglects its deficiency in normative content. As it stands, the definition of the principle specifies neither the nature of precautionary action, nor the point at which precautionary action is triggered. Whilst its underlying philosophy can provide a general guide to anticipatory environmental protection, it can be argued that it lacks the exactitude necessary to translate into a regulatory standard.

In an attempt to circumvent the problem of definitional deficit, the precautionary principle has been presented as being concerned with the way in which public decisions are made, rather than dictating a particular outcome.⁷⁵ Fisher conceptualizes the principle as one of process, thus reflecting its status as a principle

⁶⁸ Fisher, E. (2002) at page 16; see also Sunstein, C. Legal Reasoning and Political Conflict (Oxford University Press; Oxford; 1996) at page 30; and Posner, R. The Problems of Jurisprudence (Harvard University Press; Harvard; 1990) at page 44.

⁶⁹ Habermas, J. Between Facts and Norms (Polity Press; Cambridge; 1996) at page 208.

⁷⁰ Commission of the European Communities, Communication on the Precautionary Principle (EC Commission; Brussels; 2000) at pages 17-19; see also, Tridimas, T. The General Principles of EC Law (Oxford University Press; Oxford; 2000) chapter 1. ⁷¹ Dratwa, J. (2001) at page 2.

⁷² Cameron, J. as cited in Alder, J. and Wilkinson, D. (1999) at page 148.

⁷³ Boyle, A. 'Some Reflections on the Relationship of Treaties and Soft Law' (1999) 48 ICLQ 901, at page 907. ⁷⁴ *Ibid*.

⁷⁵ Fisher, E. 'Is the Precautionary Principle Justiciable?' (2001) 13(3) Journal of Environmental Law 315-334, at page 319.

not a rule - she states that "[i]t is 'not all or none in nature' - it is a 'matter of degree'."76 There is no rigid approach to applying it. Instead, its application will depend on its context, placing innovative, democratic and discretionary decisionmaking at the top of its agenda rather than being based on one-dimensional notions of legal certainty and the rules of law. This feature, as Fisher puts it, makes the precautionary principle a 'frustrating' tool of risk management⁷⁷ because its boundaries of operation are undefined. Although the precautionary principle might provide a broad guide for decision-making, its generality makes it impossible to achieve uniformity in definition or interpretation. Illustrating the tension between precautionary process and consistent interpretation requires reference to three aspects of the precautionary decision-making process. The difficulty with this interpretation of precaution as an administrative process is that it becomes exposed to pluralism beyond its stand-alone definition. The representation of precaution as a process compounds issues of implementation. As the following three paragraphs suggest, the notion of precautionary process calls for a consideration of factors outside the boundaries of its definitional framework.

First, as Schomberg points out, the precautionary principle requires a highly flexible process which can accommodate a wide range of scenarios.⁷⁸ This requires that problems encountered on a case-by-case basis are subject to deliberation, together with ongoing monitoring, and adapting standards accordingly. Deville and Harding advocate a decision-making process which compels the decision-maker to focus in more detail on the problem and its scientific uncertainties.⁷⁹ Weale *et al* highlight the relationship between the precautionary principle and the *Stand der Technik* (state of the art) principle in Germany, and argue that the application of precaution is contingent not only on the nature of the risk and scientific uncertainties, but also the state of technological advance at the time.⁸⁰

⁷⁶ Ibid.

⁷⁷ *Ibid.* at page 320.

⁷⁸ Schomberg, P. Memorandum to the House of Lords Select Committee on European Communities, Second Report: EC Regulation of Genetic Modification in Agriculture (HL11-II, 1999).

 ⁷⁹ Deville, A. and Harding, R. Applying the Precautionary Principle (Federation Press; Sydney; 1997).
 ⁸⁰ Weale, A. et al, Environmental Governance in Europe (Oxford University Press; Oxford; 2000) at page 157; see also Von Moltke, K. 'The Vorsorgeprinzip in West German Environmental Policy', in Royal Commission of Environmental Pollution, Best Practicable Environmental Option (HMSO; London; 1988) Appendix 3.

Secondly, it is widely accepted that a democratic approach to precautionary decisionmaking is desirable.⁸¹ Despite there being no agreement as to how this might be put into practice, it is recognised that a participatory process should be a permanent feature of precautionary administrative processes.⁸² The upshot of incorporating a broad range of actors in precautionary decision-making is that the concept of precaution becomes increasingly susceptible to inconsistent interpretation.

Finally, it is imperative that the process recognises that the precautionary principle has an inherent element of proportionality. In this context, Schomberg submits that the term proportionality "implies the evaluation of the scope of the measures to be taken and when they should be taken."⁸³ However, the distinction between the principle of proportionality and the precautionary principle is not always clear, further muddying the water as regards the way in which the precautionary principle is understood. Early EC case law demonstrates the failure to distinguish between the two, whereby the adoption of proportionality was actually an implicit implementation of the precautionary principle.⁸⁴ Furthermore, the EC Commission Communication claims that the notion of precaution entails proportional action.⁸⁵ The difficulty encountered in setting apart the two concepts makes defining the parameters of the operation of the precautionary principle an arduous task.

<u>1.3 Sustainable development: an equally elusive concept</u>

It is important to put the precautionary principle into the context of sustainable development. The two concepts are inexorably connected, and this is evident in the prevention of environmental degradation:-

⁸¹ Fisher, E. (2001) at page 320.

⁸² Ibid.; see also Harding, R. and Fisher, E. (eds) Perspectives on the Precautionary Principle (Federation Press; Sydney; 1999) at page 294.

⁸³ Schomberg, P. (1999).

⁸⁴ See, for example, Case C-157/96, The Queen v. Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union (and Others) 5 May 1998, European Court Reports 1998 page I-02211.

⁸⁵ EC Commission (2000) at page 3.

"The idea of sustainable development shares a common genus with numerous other emergent principles in the arena of environmental protection. For instance, prospectively, in the search for sustainable solutions, the incorporation of the notion of integration into the treaty is likely to become increasingly significant... The link between sustainable development and the precautionary principle appears especially powerful, and prior consideration is therefore given to this principle."⁸⁶

An understanding of the principle of sustainable development is undeniably crucial in the quest to understanding the precautionary principle. Hughes observes the operation of a three-fold relationship between environmental principles – the application of specific *rules*, based on accepted *general principles*, which in turn reflect *ethical values*.⁸⁷ Furthermore, Hughes notes that within this hierarchy, "it must be that sustainable development must be the first and greatest principle and that all others should serve that end."⁸⁸

Sustainable development is "a term that has come to pervade environmental policy discussions."⁸⁹ In the words of Stallworthy, it is "a process, not a scientifically definable capacity; it describes the journey we must undertake to arrive at the destination, which is of course sustainability itself".⁹⁰ Despite the fact that its meaning and value are hotly contested, it is generally accepted that sustainable development is *the* foundational principle in environmental law.⁹¹

It is argued that the notion emerged during the 1960s in the wake of the Second World War, and in response to widespread trepidation over increased industrialization and environmental damage.⁹² Reflecting this concern, the Declaration of the UN Conference on the Human Environment in Stockholm, 1972, formulated the principle of sustainable development, stating that:-

⁸⁶ Stallworthy, M. (2002) at page 47.

⁸⁷ Hughes, D. et al (2002) at page 15.

⁸⁸ *Ibid.* at pages 23-4.

⁸⁹ Alder, J. and Wilkinson, D. (1999) at page 127.

⁹⁰ Porritt, J. Playing Safe: Science and the Environment (Thames and Hudson; London; 2000) at pages 103-104.

⁹¹ See for example, Sunkin, M. et al, Sourcebook on Environmental Law (Cavendish; London; 2002) at page 46.

⁹² Elworthy, S. and Holder, J. *Environmental Protection* (Butterworths; London; 1997) at page 132

"Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of quality that permits a life of dignity and well being, and he bears a solemn responsibility to protect and improve the environment for present and future generations".⁹³

Perhaps the most significant outcome of the Stockholm Conference has been the creation of a new discourse of sustainability.⁹⁴ The concept has become an underlying element in the development of environmental law and policy, gaining credibility at domestic, European and international levels. Arguably, the imperative of sustainable development was established in the 1987 Brundtland Report of the World Commission on Environment and Development, which defined the concept as:-

"development that meets the needs of the present without compromising the ability of future generations to meet their own needs."⁹⁵

This report was a catalyst for the so-called 'Earth Summit' – including the 1992 UN Conference on Environment and Development (UNCED) and Agenda 21 – represents a significant step towards legal recognition of sustainable development. In the aftermath of UNCED, sustainable development has been "defined to death".⁹⁶ Macnaghten and Urry point out that all definitions "share the underlying belief that economic and social change is only sustainable and thereby beneficial in the long term when it safeguards the natural resources on which all development depends."⁹⁷ However, it becomes clear that, despite the development of a common language of sustainable development, it is not commonly understood. Given the inconsistencies

⁹³ Declaration of the UN Conference on the Human Environment (Stockholm) UN Doc A/CONF/48/14/REV 1, Principle 1.

 ⁹⁴ See, for example, The Nairobi Declaration on the State of Worldwide Environment (UNEP/GC.10/INF.5 of 19 May 1982); and World Charter for Nature UNGA Res. 37/7, 28 Oct 1982, reprinted in 23 ILM (1983) 455-60.
 ⁹⁵ World Commission on Environment and Development, *Our Common Future* (Oxford University)

⁹⁵ World Commission on Environment and Development, *Our Common Future* (Oxford University Press; Oxford; 1987)

⁹⁶ Stallworthy, M. (2002) at page 2.

⁹⁷ Macnaghten, P. and Urry, J. Contested Natures (Sage; London; 1998) at page 213.

and variations in localized perceptions of the concept,⁹⁸ any attempt to reach a universal definition of sustainable development is fruitless. It is argued that "the nature of the term is that it is uncertain".⁹⁹ Cullingworth and Nadin see it as a "broad political commitment to the idea of sustainability"¹⁰⁰ that has been so exhausted that "it has ceased to have any communicable meaning."¹⁰¹

Components of sustainable development are highly subjective. Central to the difference in interpretations of sustainable development are perceptions of what is 'fair' to future generations, and what future generations 'need'. As Bell and McGillivray point out, there is considerable debate about what future generations need:-

"Even where things have been treasured as 'necessary' in the past and present, this is no guarantee that future generations will 'need' or even value them."¹⁰²

Consequently, those who more optimistically see human ingenuity as solving environmental problems are likely to be more willing to exploit present natural resources.¹⁰³ Conversely, those who attribute superior value to environmental resources would be expected to recognise the irreversibility of damage and be reluctant to destroy natural resources. The problem is that there will never be a consensus on values, even if values did not change temporally.

As a result of the failure to pin-point one meaning, definitions of sustainable development vary immensely across a wide spectrum. Distinctions can be made between 'strong' and 'weak' interpretations of sustainable development. A 'strong' interpretation requires that future generations have the same environmental resources

⁹⁸ Voisey, H. and O'Riordan, T. Sustainable Development in Western Europe: Coming to Terms with Agenda 21 (Frank Cass Publishers; London; 1997) at pages 25-40.

Stallworthy, M. (2002) at page 2.

¹⁰⁰ Cullingworth, B. J. and Nadin, V. Town and Country Planning in the UK (Routledge; London; 1997) at page 164.

¹⁰¹ *Ibid*.

¹⁰² Bell, S. and McGillivray, D. (2000) at page 45. See also, Bell, S. and McGillivray, D. *Environmental Law* (Oxford University Press; Oxford; 6th edition; 2005) at pages 62-3 where the authors observe that was is meant by the 'needs and aspirations' (Brundtland Report 1987) of future generations is unclear. ¹⁰³ *Ibid*.

as we ourselves inherited.¹⁰⁴ It places the value of environmental resources above all others, drawing attention to the extent to which those resources are irreplaceable.¹⁰⁵ Weak versions call for distributive justice between generations, obliging the present generation to pass onto the next an equivalent or better pool of resources.¹⁰⁶ Provided the overall result is positive, this interpretation permits trade-offs between resources and accepts that certain resources may be sacrificed. An intermediate position would require us to leave the next generation the same options available to us.¹⁰⁷

O'Riordan and Cameron note that this distinction between weak and strong sustainability "lies in the degree to which the precautionary principle ... is applied."¹⁰⁸ Likewise, the distinction between weak and strong precaution must depend on whether a weak or strong approach to sustainable development is elected.¹⁰⁹ The interpretation of the precautionary principle is confined by the parameters of sustainability.

Whilst the notion of precaution is universally acknowledged, its interpretation and operation vary greatly.¹¹⁰ It is argued that:-

"[t]here is neither an agreed yardstick, nor a consensus as to how it should be applied."¹¹¹ They go on to state that "[i]t is not the fault of the precautionary principle that it is in a muddle. The confusion is an inescapable part of the modern environmental dilemma."¹¹²

¹⁰⁴ See Alder, J. and Wilkinson, D. (1999) at page 129.

¹⁰⁵ Bell, S. and McGillivray, D. (2000) at page 44.

 ¹⁰⁶ See Alder, J. and Wilkinson, D. (1999) at pages 129-130.
 ¹⁰⁷ *Ibid*.

¹⁰⁸ O'Riordan, T. and Cameron, J. (1994) at page 19.

¹⁰⁹ See Turner, R. K. *et al, Environmental Economics: An Elementary Introduction* (Harvester Wheatsheaf; London; 1994) which, at page 59, diagrammatically represents the relationship between precaution and sustainable development, and illustrates that definitions of the precautionary principle vary within the limits of the interpretation of sustainable development.

¹¹⁰ O'Riordan, T. and Cameron, J. (1994) at page 21.

¹¹¹ *Ibid*.

¹¹² *Ibid*.

To some extent, the same can be said of sustainable development. Despite its widespread acceptance:-

"no-one can properly put it into operation, let alone define what a sustainable society would look like in terms of political democracy, social structure, norms, economic activity, settlement geography, transport, agriculture, energy use and international relations."¹¹³

This ambiguity relating to the implementation of sustainable development has major implications for attempts to precisely define and apply the precautionary principle – since both concepts are necessarily related to one another.¹¹⁴ The Bergen Declaration¹¹⁵ explicitly forged the link, stating that "[i]n order to achieve sustainable development, policies must be based on the precautionary principle."¹¹⁶

Given that achieving a common understanding of the application of sustainable development has been identified as an arduous task, interpreting precaution is equally problematic. Because the underlying aim of sustainable development is construed inconsistently, translations of the precautionary principle will also vary. One's understanding of sustainable development will inevitably influence one's understanding and application of precaution. Acknowledgement of the ambiguity of the concept of sustainable development provides an explanation for the incoherence and diversity of definitions of the precautionary principle.

• <u>1.4 (Alleged) German roots</u>

There is an extensive body of literature tracing the evolution of the precautionary principle. The overriding contention is that the principle has its roots in German

¹¹³ O'Riordan, T. et al, Reinterpreting the Precautionary Principle (Cameron May; London; 2000) at page 41.
¹¹⁴ Alder, J. and Wilkinson, D. (1999) at page 149; see also Elworthy, S. and Holder, J. (eds) (1997) at

¹¹⁴ Alder, J. and Wilkinson, D. (1999) at page 149; see also Elworthy, S. and Holder, J. (eds) (1997) at page 154.

¹¹⁵ Bergen Declaration on Sustainable Development in the ECE Region UN Doc A/CONF.151/PC/10 (1990) 16th May 1990, in Hohmann, H. (ed) *Basic Documents of International Environmental Law Vol. l* (Graham & Trotman; London; 1992) at 558-559.

¹¹⁶ Ibid.

legislation adopted during the mid-1970s,¹¹⁷ although as the Chapter Four suggests, it first emerged in a domestic context in Sweden in 1969. Freestone, for example, claims that "[t]he origins of the precautionary principle ... appear to lie in concepts of national law, notably the German law *Vorsorgeprinzip*, which some also regard as the most important principle of German environmental policy."¹¹⁸ O'Riordan and Cameron also maintain that the principle emanates from the German concept of Vorsorge, which, when translated, literally means 'beforehand or prior care or worry', implying caution, good household management, and provision for the future.¹¹⁹ Furthermore, Boehmer-Christiansen states that "[t]he precautionary principle is said to have made its way into English during the early 1980s as the translation of the German Vorsorgeprinzip.¹²⁰

The Vorsorgeprinzip is one of five key principles of German environmental policy – namely Vorsorge, Verursacherprinzip (polluter pays), Kooperation (consensus), Wirtschaftliche Vertretbarkeit (principle of proportionality), and Gemeinlast prinzip (common burden principle).¹²¹ The concept of Vorsorge finds its roots in the first draft of the new clean air legislation of 1970 – which states an intention to *dem Enstehen schadlicher Umwelteinwirkungen vorzubeugen* – to prevent the development of harmful environmental effects.¹²² The subsequent Federal Government Umweltprogramm of 1971 expresses the same notion – long term planning for the environment.¹²³ In 1974, Parliament passed clean air legislation implementing the term 'vorsorgeprinzip' in response to growing concern over the irreversible nature of damage to habitats caused by acid rain and photochemical smog.¹²⁴ Quintessentially, the principle required precautionary action in situations of potentially serious or irreversible risks to health or the environment before there was evidence of possible harm, with regard to the conceivable costs and benefits of action

¹¹⁷ See for example Th. Douma, W. (1996) 'The Precautionary Principle' <u>http://www.eel.nl/virtue/precprin.htm</u>, accessed April 2000.

¹¹⁸ Freestone, D. 'The Precautionary Principle', in Churchill, R. and Freestone, D. International Law and Global Climate Change (Graham & Trotman; London; 1991) at page 21.

¹¹⁹ See O'Riordan, T. and Cameron, J. (eds) (1994) at page 12; and also Tromans, S. 'High Talk and Low Cunning: Putting Environmental Principles into Legal Practice' (1995) 2 *Journal of Planning Law* 779-796 at page 780.

¹²⁰ Boehmer-Christiansen, S. 'The Precautionary Principle in Germany – Enabling Government, in O'Riordan, T. and Cameron, J. (eds) (1994) chapter 2 at page 31.

¹²¹ Ibid. at page 33.

¹²² Wey, K. G. Umweltpolitik in Deutschland (Westdeutscher Verlag; Opladen; 1993) at page 207

¹²³ Boehmer-Christiansen, S. (1994) at page 35.

¹²⁴ The German Clean Air Act 1974.

or inaction.¹²⁵ A subsequent report on the Clean Air Act explained that 'vorsorgeprinzip' called for elements such as research and monitoring of potential hazards; the proportionality principle, where the costs of the prevention of hazards should be proportionate to the likely benefits gained; and the reducing of risks before full proof of harm is established, should its impacts be serious or irreversible.¹²⁶ Vorsorge was defined as following:-

"The principle of precaution commands that the damages done to the natural world (which surrounds us all) should be avoided in advance and in accordance with opportunity and possibility. Vorsorge further means the early detection of dangers to health and environment by comprehensive, synchronized (harmonized) research, in particular about cause and effect relationships..., it also means acting when conclusively ascertained understanding by science is not yet available. Precaution means to develop, in all sectors of the economy, technological processes that significantly reduce environmental burdens, especially those brought about by the introduction of harmful substances."¹²⁷

However, although mainstream literature tends to treat the precautionary principle as a manifestation of *Vorsorge*prinzip, this theory does not satisfactorily account for the extensive variation in its definition and interpretation. Another explanation, which develops the *Vorsorgeprinzip* argument, is that the precautionary principle has developed independently in different jurisdictions, producing a patchwork of different interpretations. There is evidence that the principle is being simultaneously developed at the sub-national,¹²⁸ national,¹²⁹ EC,¹³⁰ and international level.¹³¹ The

¹²⁵ European Environment Agency (EEA), Late Lessons from Early Warnings: the Precautionary Principle 1896-2000 (EEA; Brussels; 2001) at page 13.

¹²⁶ Federal Interior Ministry 1984 Dritter Immissionsschutzbericht, Drucksache, Bonn 10/1345, at 53. See Boehmer-Christiansen, S. (1994) at page 36; EEA (2001) *Ibid.* at page 13.

 ¹²⁷ Federal Interior Ministry 1984 Dritter Immissionsschutzbericht. Drucksache, Bonn 10/1345 at 53.
 Approximate translation in Boehmer-Christiansen, S. (1994) *Ibid.* at page 37.
 ¹²⁸ Walter, W. (The Branch, S. (1994) *Ibid.* at page 37.

¹²⁸ Walton, W. 'The Precautionary Principle in the UK Planning System' (1995) 7(1) Environmental Law and Management 35-40.

¹²⁹ Th. Douma, W. 'The Precautionary Principle in the Netherlands', in O'Riordan, T. *et al* (2000) at page 163, and De Sadeleer, N. 'The Enforcement of the Precautionary Principle in German, French and Belgian Courts' (2000) 9(2) *Review of European Community and International Environmental Law* 144.

¹³⁰ Commission of the European Communities, *Communication on the Precautionary Principle* COM 1(2000) final (EC Commission; Brussels; 2000)

way it is interpreted and implemented varies considerably, and thus, it is by no means clear how a common understanding or definition should be achieved.¹³² Its recognition and implementation spans international boundaries – India¹³³, Canada,¹³⁴ Australia,¹³⁵ and the US have a long history of precautionary philosophy.¹³⁶ Consequently, the precautionary principle is enshrined in a large number of legal and policy definitions,¹³⁷ although its role in anticipating hazards remains unclear. Stone claims that there is no such thing as 'the' precautionary principle because of the infinitely-differing versions of the principle, no one version being "elastic enough to wrap around all alternative institutional needs."¹³⁸ Furthermore, there have been claims that "the search for a 'common understanding' is a futile exercise since the principle is nonsensical and non-existent".¹³⁹

Against this background, this thesis argues that a fundamental impact of this definitional deficit is inconsistency in the manner in which the relationship between the precautionary principle and risk assessment is construed. This provokes a consideration of the interface between notions of risk, science, and precaution, which is considered in detail in Part Two. Chapters Two to Five introduce the precautionary principle in international, EC and domestic spheres. An underlying question in each chapter is the extent to which scientific risk assessment is seen to determine the operation of precaution.

¹³¹ Fisher, E. (2002) at page 112; Cameron, J. 'The Precautionary Principle in International Law' in O'Riordan, T. and Cameron, J. (1994) at page 113.

¹³² See Fisher, E. (2002) *Ibid*.

¹³³ Vellore Citizens Welfare Forum v. Union of India (1997) 9(2) Journal of Environmental Law 387; and AP Pollution Control Board v. Nayudu [1999] (1) UJ (SC) 426.

¹³⁴ Ogilvie, K. Applying the Precautionary Principle to Standard Setting or Toxic Substances in Canada (Pollution Probe 2001).

¹³⁵ Harding, R. and Fisher, E. (1999)

¹³⁶ Raffensberger, C. and Tickner, J. (eds) *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Island Press; Washington D.C.; 1999).

¹³⁷ See Vanderzwaag, D. 'The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces' (1999) 8 Journal of Environmental Law and Practice 355.

¹³⁸ Stone, C. D. (2001).

¹³⁹ Fisher, E. (2002) at page 15.

<u>Chapter Two</u> <u>The precautionary principle in international environmental</u> <u>protection</u>

2.0 Introduction

As Chapter One suggests, the definition of the precautionary principle is notoriously vague and varying. Nowhere is this more evident than in international law. The following chapter traces the adoption of precautionary-type thinking in an international instrument to the early 1970s, monitoring its development to the height of its global recognition as Principle 15 of the 1992 Rio Declaration. It shows that its universal acceptance has failed to result in its universal interpretation. This chapter illustrates the way in which international environmental provisions define the precautionary principle in vastly dissimilar ways. In doing so it charts the development of Principle 15 throughout the UN Preparatory Committee negotiations, and discovers the 'main players' responsible for determining its final definition. Remarkably, despite the fact that Principle 15 is considered within academic circles to represent the definitive interpretation of precaution, the UN in its Terminology Bulletin, produced in conjunction with the Rio Declaration, presents a very different definition. This is evidence not only of the lacking consensus as to its meaning, but also of the emptiness of definitions of the precautionary principle. Essentially, the failure of definitions to prescribe the requirements of precautionary action makes its application wholly discretionary. To a large extent, the international courts have recognised its lacking normativity, and have, as a result, been reluctant to construe the precautionary principle as imposing any *legal* obligation in customary law.

The aim of this chapter is to provide evidence to support the argument made in Chapter One that the precautionary principle is presented as having a number of different meanings. It focuses specifically on Principle 15 of the Rio Declaration and highlights the distinction between the definitions proposed by the US and the EC prior to the UN Conference on Environment and Development (UNCED). This transatlantic divide has been the subject of extensive debate. However, this thesis

departs from the bulk of existing literature which compares the 'strong' precautionary approach endorsed by the EC with the 'weaker' approach advocated by the US. Although this thesis acknowledges that the strong/weak dichotomy emerges from the definitional deficit of precaution, its primary interest is the impact of this definitional ambiguity on the interrelationship between risk assessment and the application of the precautionary principle. Although this chapter is only a broad consideration of the notion of precaution in the international sphere, it forms a basis for Chapter Three which draws out the specific theme of the dependence of precaution on scientific risk assessment. The overriding argument is that, although the definitional deficit of precaution can manifest itself in a number of different ways - such as, inconsistent interpretations of 'threats', 'serious or irreversible' and 'damage' - one of the most fundamental implications of this imprecision is that it creates an indeterminate relationship between conventional risk assessment and the precautionary principle. This is significant because it renders uncertain the point at which precautionaryterritory is entered into. The existence of ambiguity in relation to the 'trigger' of precautionary action raises profound questions about the role of scientific risk assessment in the prediction and control of future hazards. These issues are discussed in further detail in Part Two of this thesis. For now, however, it is enough to highlight that the definitional deficit of precaution forces a deeper consideration of broad theoretical concerns that are often overlooked by precautionary literature.

With these issues in mind, this chapter seeks to introduce the precautionary principle in the context of the diversity with which it is formulated in international provisions. Armed with an insight into its breadth of definition, Chapter Three goes on to give a detailed analysis of what I consider to be a fundamental consequence of divergent interpretations of precaution: inconsistencies in the way in which the affiliation between the precautionary principle and risk assessment is perceived.

2.0 A principle of international origin

Despite the argument that it derives from German jurisdiction, the precautionary principle is traditionally described as a principle of international origin, which reflects

the theory that risks in the modern era are global rather than local.¹ From this perspective, and given the potentially widespread scale of environmental degradation in contemporary society, the precautionary principle has particular resonance on the international forum. Unsurprisingly, the contention that environmental hazards disregard international boundaries has placed increasing demands on collective decision-making and burden-sharing, calling for the establishment of universal The tendency for modern environmental risks to escape regulatory standards. conventional spatial limitations means not only that their impact extends beyond the source, but also that the dispersion of impact makes it increasingly difficult to locate responsibility. The result is twofold. First, as O'Riordan and Cameron note, the only way in which to safeguard against 'globalized risk'² is to ensure that all nations agree to the same terms of compliance.³ Second, it has been recognised that the problem of locating responsibility is best dealt with by an anticipatory, as opposed to a The combination of both has culminated in the reactionary, response to risk. emergence of the concept of precaution in international treaties and agreements.

2.1.2 Tracing its emergence

At international level, the precautionary-type mindset can be traced to the 1972 Declaration of the UN Conference on the Human Environment held in Stockholm,⁴ which held as its underlying thesis the notion that "we must shape our actions throughout the world with a more prudent care for their environmental consequences."⁵ In particular, Principle 21 of that Declaration lays emphasis on the importance of establishing the absence of environmental risk prior to action, stipulating that, whilst States have the right to exploit their own resources, they have a concurrent obligation "to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States."⁶ This pre-emptive sentiment

¹ Majone, G. 'What Price Safety? The Precautionary Principle and its Policy Implications' (2002) 40(1) JCMS 89-109, at page 89.

² Beck, U. Risk Society (Polity Press; Cambridge; 1992).

³ O'Riordan, T. and Cameron, J. (eds) Interpreting the Precautionary Principle (Cameron May; London; 1994)) at page 200.

⁴ UN Doc A/CONF.48/14/Rev.1.

⁵ UN Doc A/CONF.48/14/Rev.1 paragraph 6.

⁶ UN Doc A/CONF.48/14/Rev.1.

was reinforced when, in the aftermath of the Stockholm Declaration, a World Commission on Environment and Development Experts Group on Environmental Law recommended the alteration of its language so as to include the requirement of an 'effects assessment' *before* the authorisation of potentially hazardous activities.⁷

A decade later, a precautionary philosophy was adopted by the UN in its World Charter for Nature.⁸ Reflecting the anticipatory ethos of the Stockholm Declaration, Principle 11(b) of the Charter stipulates that activities likely to pose a 'significant risk' to nature shall:-

"be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed."⁹

Despite the fact that, by the early 1980s, the notion of anticipatory action was prevalent,¹⁰ the first international agreements to make reference to the notion of precaution were the Declarations of International Conferences on the Protection of the North Sea. Whereas the First Declaration following the Conference at Bremen in 1984 cites the concept of 'vorsorgemassnahmen' (translated in the English text as 'timely preventive measures'),¹¹ the Second and Third Declarations, of 1987 and 1990 respectively, expressly cite the concept of precaution.¹² The Second Declaration explains that application of 'the principle of precautionary action' is required when 'there is reason to assume that certain damage or harmful effects on the living

⁷ See World Commission on Environment and Development (WCED) Experts Group on Environmental Law, *Environmental Law and Sustainable Development: Legal Principles and Recommendations* (WCED; 1996) at page 58; see also Daemen, T. J. 'The EC's Evolving Precautionary Principle – Comparisons with the United States and Ramifications for Doha Round Trade Negotiations' (2003) *European Environmental Law Review* 6-19, at page 6.

⁸ UN Doc A/RES/37/7 1982.

⁹ emphasis added.

¹⁰ See, for example, the Preamble to the Vienna Convention for the Protection of the Ozone Layer (1985) UNEP Doc. 19.53/5; and, the Preamble to the Montreal Protocol on Substances that Deplete the Ozone Layer (1987)

¹¹ Preamble to the First Declaration, see Gundling, L. 'Status in International Law of the Principle of Precautionary Action' (1990) 5 International Journal of Estuarine and Coastal Law 23-30, at page 24

¹² Ministerial Declaration of the Second International Conference on the Protection of the North Sea, London 1987; and Ministerial Declaration of the Third International Conference on the Protection of the North Sea, The Hague, 1990 (see (1990) 1 Yearbook of International Environmental Law 658, at pages 662-73.

resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects".¹³ The Preamble to the Third Declaration is rather more specific, defining the scope of its application more narrowly as "tak[ing] action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects."¹⁴

The Vienna Convention for the Protection of the Ozone Layer,¹⁵ which was opened for signature in March 1985 and came into force in September 1988, states in its Preamble that it is "[m]indful also of the precautionary principle measures for the protection of the ozone layer". In 1989, the Nordic Council's Conference on the Pollution of the Seas acknowledged the need for "an effective precautionary approach", stating that the precautionary principle is:-

"intended to safeguard the marine ecosystem by, among other things, eliminating and preventing pollution emissions where there is reason to believe that damage or harmful effects are likely to be caused, even where there is inadequate in inconclusive evidence to prove a causal link between emissions and effects."¹⁶

Indeed, by 1990, the UN Secretary-General was able to report that the precautionary principle "has been endorsed by virtually all recent international forums."¹⁷

It is interesting that a number of international instruments have equated the precautionary principle with the concept of prevention. The Bamako Convention,¹⁸ a prime example, requires that "each party shall strive to adopt and implement *the*

¹³ Second Declaration, at paragraph XVI(1).

¹⁴ Third Declaration (1990).

¹⁵ UNEP Doc.19.53/5.

¹⁶ Final Report of the Nordic Council's International Conference on the Pollution of the Seas: Final Document Agreed on 18 October 1989, 99 app. v. (1990).

¹⁷ As cited in a UNEP publication: *Relevance and Application of the Principle of Precautionary Action* to the Caribbean Environment Programme, CEP Technical Report No.21 (1993) at paragraph I. For a recent application of precaution in international policy, see 'International Law Association Resolution 3/2002: New Delhi Declaration Of Principles Of International Law Relating To Sustainable Development' (2002) 2 International Environmental Agreements: Politics, Law and Economics 211– 216, Article 4.

¹⁸ Bamako Convention on the Ban of Imports into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa 1991.

preventive, precautionary approach to pollution problems".¹⁹ The Oslo and Paris Commission Convention for the Protection of the North-East Atlantic also makes a direct comparison, stating that:-

"[t]he Contracting Parties shall apply: (a) the precautionary principle, by virtue of which *preventive measures* are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may bring about hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with other legitimate uses of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and the effects".²⁰

However, as Young notes, the principle of precaution goes beyond the conventional objective of merely preventing environmental damage once the risk of such damage is known.²¹ As such, the precautionary principle requires the taking or prohibition of action while there is still *uncertainty* as to the existence and magnitude of a risk. Whereas preventive action is employed in the face of a quantitatively known (calculable) risk, precautionary action is associated with quantitatively unknown (incalculable) risk, i.e. uncertainty. Prevention and precaution, therefore, are distinct types of regulatory response by virtue of a difference in the degree of knowledge required before invocation. The tendency for international instruments to treat prevention and precaution as being one and the same thing creates deep-seated ambiguity as to the point at which a precautionary approach is triggered. The failure by international provisions to make a clear distinction results in some doubt as to the certainty with which a risk must be known before acting.

This is a significant problem. The precautionary principle itself does not dictate with any meaningful degree of specificity the point at which it comes into operation. Whilst the blurred precaution/prevention distinction draws attention to the ambiguity

¹⁹ Article 4(3)(f), emphasis added.

²⁰ 1992 Article 2(2)(a), emphasis added.

²¹ Young, M. D. For Our Children's Children: Some Practical Implications for Inter-Generational Equity and the Precautionary Principle (Resource Centre Assessment Commission; Canberra; 1993) at page 14.

in relation to requisite levels of scientific certainty, the problem exists even in the absence of any explicit connection with prevention. Definitions of precaution stipulating that its application is triggered by 'scientific uncertainty' prescribe neither the extent nor the nature of uncertainty required. Indeed, the level of generality with which it is phrased induces problems with implementation. Nollkaemper reminds us that principles serve as guidelines as opposed to imposing concrete obligations and that they do not require a particular decision.²² However, there is a fundamental problem with the assumption that the elusive nature of precaution is implicit authorisation for the exercise of discretion in determining the appropriate extent and nature of scientific uncertainty for the implementation of precaution. From an operational aspect, ambiguity relating to its point of application generates deep-seated questions about the role of scientific risk assessment in determining the appropriate implementation of precaution. Subsequent chapters add substance to this argument.

2.1.2 Intrinsic relativity

The intrinsic relativity of precaution is illustrated by Bell and McGillivray, who rightly point out that:-

"each convention tends to contain a slightly different formulation of the principle, which makes it difficult to identify an interpretation with which all states can be said to agree implicitly as a matter of binding international law."23

A degree of international consensus in relation to the core philosophy of precaution, however, was marked by the signing of five environmental instruments following the 1991 United Nations Conference on Environment and Development in Rio de Janeiro. These included two legal instruments - the UN Framework Convention on Climate Change;²⁴ and the Convention on Biological Diversity²⁵ – and three non-binding

²² Nollkaemper, A. "What You Risk Reveals What You Value" and Other Dilemmas Encountered in the Legal Assault on Risk', in Freestone, D. and Hey, E. (eds) (1996) 75, at page 80.

²³ Bell, S. and McGillivray, D. Environmental Law (Blackstone Press; London; 5th edition; 2000) at page 48. ²⁴ New York, 9 May 1992 (1992) 31 ILM 849; 161 signatories.

agreements – Agenda 21;²⁶ the Rio Declaration on Environment and Development;²⁷ and the Statement of Principles for a Global Consensus on the Management, Conservation and Sustainable Development of All Types of Forests.²⁸ All but the latter incorporated the precautionary principle.

2.2 Principle 15: the preparatory process

Arguably, Principle 15 of the Rio Declaration is the most commonly accepted definition of the precautionary principle.²⁹ Cameron and Abouchar even go as far as claiming that Principle 15 is so prevalent that it has developed into a component of customary international law.³⁰ Given its pervasiveness, it is perhaps fitting to examine its evolution during the negotiations preceding the finalising of the Declaration in 1992. In the two years prior to Rio, the UNCED Preparatory Committee ('Prepcom'), which was divided into three working groups, met four times to propose and modify agreements in relation to the environment and development, and to provide a forum upon which concrete action plans could be established amongst participating States and international organisations. The first substantive session was held in Nairobi in August 1990, and was followed by a second and third session in Geneva in March and August 1991 respectively, and a fourth in New York early in 1992 during which the Prepcom embarked upon the drafting of the Declaration.³¹

A reading of the preparatory documents sheds light on the process leading to the formulation of Principle 15. Like other international agreements, the Prepcom

²⁵ Rio de Janeiro, 5 June 1992, (1992) 31 ILM 818; 170 signatories.

²⁶ Rio de Janeiro, 16 June 1992 UN Doc. A/CONF.151/26, Vol.III (1992).

²⁷ Rio de Janeiro, 14 June 1992 (1992) 31 *ILM* 874.

²⁸ Rio de Janeiro, 13 June 1992 (1992) 31 *ILM* 881.

 ²⁹ See, for example, deFur, P. L. and Kaszuba, M. 'Implementing the Precautionary Principle' (2002)
 288 The Science of the Total Environment 155-165, at page 157; and Conko, G. 'Safety, Risk and the Precautionary Principle: Rethinking Precautionary Approaches to the Regulation of Transgenic Plants' (2003) 12 Transgenic Research 639-647, at page 641.
 ³⁰ Cameron, J. and Abouchar, J. 'The Status of the Precautionary Principle in International Law', in

³⁰ Cameron, J. and Abouchar, J. 'The Status of the Precautionary Principle in International Law', in Freestone, D. and Hay, E. (eds) (1996) chapter 3, at page 41; De Sadeleer, N. 'The Effect of Uncertainty on the Threshold Levels to which the Precautionary Principle Appears to be Subject', in Sheridan, M. and Lavrysen, L. (eds) *Environmental Law Principles in Practice* (Bruylant; Bruxelles; 2002) chapter 1 at page 21.

³¹ Kovar, J. D. 'A Short Guide to the Rio Declaration' (1993) 4 Colorado Journal of International Environmental Law and Policy 119-140, at page 120.

considered the precautionary principle to be rooted in the preventive paradigm. In particular, it traced the emergence of the precautionary principle to the Nairobi Declaration of 1982^{32} – which, although not explicitly citing the precautionary principle, highlighted the importance of prevention to international environmental policy.³³ Similarly, the definition of precaution contained in the 1990 Bergen Declaration³⁴ was considered to be pivotal in the formulation of Principle 15. Paragraph 7 of the first Annex to the Bergen Declaration required that:-

"[w]here there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation."³⁵

As well as taking into account the concept of precaution as it appeared in other international instruments, the Prepcom meetings provided a forum upon which participating States were invited to submit their own recommendations and definitions. A number of proposals of general principles submitted by participating states either fail to acknowledge the precautionary principle,³⁶ or merely pay it lipserve, failing to explain how it is intended to operate in practice. The Australian proposal, for example, simply refers to "[t]he precautionary principle and with it the promotion of full use of environmental impact statements".³⁷ Similarly, the proposal put forward by Canada acknowledges the principle but fails to give guidance as to its operation, stating that "[a]ll individuals, organizations and States shall adopt precautionary and preventive approaches".³⁸ The Chilean proposal is of slightly more practical use, connecting the precautionary principle with risk assessment, but it is not clear on their relationship:-

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³² PrepCom A/CONF.151/PC/78, Annex, at paragraph 3. Nairobi Declaration adopted by the UNEP Governing Council at its Session of a Special Character, 18 May 1982, UN Doc A/37/25 (1982).

³³ Annex II paragraph 9.

³⁴ Bergen Declaration on Sustainable Development in the ECE Region (1990).

³⁵ Annex I paragraph 7.

³⁶ See proposal submitted by China and Pakistan, Preparatory Committee Fourth Session Agenda Item 3, 4 March 1992, UN Doc A/CONF.151/PC/WG.III/L.20 Principles on General Rights and Obligations.

 ³⁷ Preparatory Committee for UNCED Working Group III Agenda Item 4 Principles on General Rights and Obligations UN Doc A/CONF.151/PC/WG.III/L.8/Rev.1, 30 Aug 1991) at paragraph 48.
 ³⁸ *Ibid.* at paragraph 49.

"States, international organizations and transnational corporations shall have the obligation to take precautionary and preventive measures regarding activities that may cause environmental damage. Prior assessment of environmental risks and notification of those concerned or potentially affected shall be undertaken"³⁹

Recognising that the proposed definitions tended to be vague and lacking in practical context, the Preparatory Committee introduced other possible elements to the precautionary principle. It suggested first, that decisions should be guided by "careful evaluation, so as to avoid, wherever practicable, serious or irreversible damage to the environment"; and second, that a "prior assessment of the risk-weighted consequences" is conducted.⁴⁰ Neither was adopted in the final UNCED definition.

The ambiguity and conflicting nature of the proposed definitions was reflected in an attempt made by the Chairman to summarise the alternative versions submitted. The Draft Principles stated that:-

"In order to [protect] [enhance the protection of] the environment, the precautionary approach [shall] [should] be widely applied [by States] [according to their capabilities]. [Where there are threats of serious or irreversible damage, lack of full scientific certainty [shall] [should] not be used as a reason for postponing [cost-effective] measures to prevent environmental degradation.]"⁴¹

A month later, a second recital of the Draft Principles proposed by the Chairman illustrated that the definition of the precautionary principle had gained some specificity. It read as follows:-

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are

³⁹ *Ibid.* at paragraph 50.

⁴⁰ Preparatory Committee for UNCED Fourth Session Working Group III Agenda Item 3 UN Doc A/CONF.151/PC/WG.III/L.24, 5 March 1992.

⁴¹ Preparatory Committee UNCED Fourth Session Agenda Item 3 UN Doc A/CONF.151/PC/WG.III/L.33, 31 March 1992, *Principles on General Rights and Obligations* – Draft Principles Proposed by the Chairman, see Principle 12.

threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.⁴²

Rejecting the attempts made by some European countries to endorse a precautionary 'principle',⁴³ UNCED finally adopted precautionary 'approach'. Whilst some commentators consider that the principle/approach distinction is significant⁴⁴ – distinguishing between the definite use of 'the' precautionary *principle* and the indefinite use of 'a' precautionary *approach* – it transpires that the consequence of this rhetorical disparity has been largely immaterial. Despite Principle 15 embracing 'a precautionary *approach*', it has come to represent a universal definition of the precautionary *principle*.

It is also worth noting that there existed a clear conflict between US and EC interpretations of precaution in terms of the degree to which it was perceived as being mandatory. Whereas the US proposal concluded that "lack of full scientific certainty *should* not be used as a reason in itself for postponing effective measures to prevent environmental degradation",⁴⁵ the EC submitted that "lack of full scientific certainty *shall* not be used as a reason for postponing measures to prevent environmental degradation".⁴⁶ The use of 'should' by the US implied that the application of the precautionary principle was perceived as involving some discretion, whilst the EC's use of 'shall' indicated that its application was perceived as being obligatory. This can be read as being evidence of a greater commitment on the part of the EC to the concept of precaution, this being subsequently reflected in 1993 during the Uruguay Negotiations when the EC campaign to include the precautionary principle in the SPS Agreement was opposed by the US.

⁴² Preparatory Committee UNCED Fourth Session Agenda Item 3 UN Doc A/CONF.151/PC/WG.III/L.33/Rev.1, 2 April 1992, *Principles on General Rights and Obligations* – Draft Principles Proposed by the Chairman, see Principle 15.

⁴³ Kovar, J. D. (1993) at page 134.

⁴⁴ Adams, M. D. 'The Precautionary Principle and the Rhetoric Behind It' (2002) 5(4) Journal of Risk Research 301-316) at page 305.

⁴⁵ A/CONF.151/PC.WG.III/L.21, 4 March 1992, Prepcom for UNCED, 4th Session Working Group III, Agenda Item 3, New York, Principle 6.

⁴⁶ A/CONF.151/PC/WG.III/L.25, 6 March 1992 Prepcom for UNCED, Fourth Session WG.III Agenda Item 3, New York, at paragraph 6.

Other than minor changes made to the sentence order, the final definition adopted by the Preparatory Committee on 2nd April 1992 largely reflected the EC proposal.⁴⁷ However, it is worth noting that the UNCED Principle 15 notably departs from the EC proposal (as well as from Annex I Paragraph 7 of the Bergen Declaration) on two counts – first, by limiting the obligation to take precautionary measures according to the 'capabilities' of Member States; and second by requiring that precautionary measures be 'cost-effective'. In this sense, Principle 15 introduces context-dependent criteria that have the capacity to severely constrain its application. This stipulation that the operation of the principle is means-tested and contingent on benefits outweighing costs inevitably yields a significantly weaker version of the precaution than one without qualification.

In the light of evidence available from Preparatory Committee sessions, it transpires that these additional conditions were introduced in a *revised* proposal submitted by China and Pakistan.⁴⁸ The original draft presented on behalf of the countries of G77 by China and Pakistan failed to include the precautionary principle in its list of Principles on General Rights and Obligations.⁴⁹ When it resubmitted its proposal 15 days later, it confined the application of the precautionary principle to situations in which preventive action is 'cost-effective', and required that its operation be dependent on 'different socio-economic contexts'.

It is important that these additional provisos are read in view of the fact that the G77 and China rejected the title 'Earth Charter', primarily because it placed too much emphasis on the needs of the environment as opposed to the needs of social development.⁵⁰ Conversely, representatives from more economically developed countries claimed that the Rio Declaration should shift its focus from anthropocentric causes to one which integrated environmental concerns. The Preamble to the Canadian proposal for an Earth Charter, for example, stipulated that an understanding of our common future should be based on "the fundamental inseparability of

⁴⁷ See A/CONF.151/PC/WG.III/L.25, 6 March 1992, Fourth Session, Working Group III Agenda Item 3, New York, Principles on General Rights and Obligations, Proposal Submitted by Portugal on Behalf of the State Members of the European Community, at paragraph 6.

⁴⁸ UN Doc A/CONF.151/PC/WG.III/L.20/Rev.1, at Principle 12.

⁴⁹ UN Doc A/CONF.151/PC/WG.III/L.20.

⁵⁰ Kovar, J. D. (1993) at page 123.

humankind *from all of nature*.⁵¹ Unsurprisingly, this was strongly resisted by the G77 and China, who claimed that developed states had failed to take into account the plight of developing countries, and were adamant that the prime concern of UNCED should be *people* and not nature.⁵² The final version of the Declaration mirrored the anthropocentricity of proposals submitted by developing countries, Principle 1 acknowledging that "[h]uman beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature."

Interestingly, in spite of the fact that the formulation of Principle 15 indicated a degree of consensus in relation to the meaning of a precautionary approach, the UN Terminology Bulletin, prepared in conjunction with UNCED 1992, presented a different definition, stating that:-

"[when] confronted with serious or irreversible threats to the environment, the absence of absolute scientific certainty should not serve as a pretext for delaying the adoption of measures to prevent environmental degradation."⁵³

The significance of this vaguely similar, although diverging, definition is profound. It provides evidence that, although there is some agreement as to its underlying philosophy of prudence, definitions of the precautionary principle are largely empty. Despite having both been prepared by UNCED, the Bulletin defined precaution using such obviously different language that it suggests that the underlying ethos of precaution was deemed to have greater import than its definition. From this perspective, the value of precaution lies not in its precise definition, but in its basic premise. The meaning of the precautionary principle exists in its concept, not in its

⁵¹ Principles on General Rights and Obligations, Preparatory Committee for the United Nations Conference on Environment and Development, Proposal Submitted by Canada, Fourth Session, Agenda Item 3, UN Doc. A/CONF.151/PC/WG.III/L.23 (1992); see also Principle II of Working Group on Ethics, Development and the Environment of the U.S. Citizen's Network on UNCED, The Earth Charter (Draft) (1991) defines 'Global Interdependence' as "[t]he Earth community, of which humankind is a part, functions in interrelated cycles, processes, and systems upon which life depends. This reality forms a basis for all social, cultural, scientific, economic, legal, and political arrangements."

⁵² Kovar, J. D. (1993) at page 124.

⁵³ UNCED, *Terminology Bulletin* No.344, Vol.1, Environment and Development UN Publication ST/CS/SER.F/344 1992.

specific expression. It might be argued, therefore, that the only way in which to define precautionary action is by describing that which has already been carried out - making definitions of precaution descriptive, not prescriptive. This lack of normativity has significant bearing on the legal status of the precautionary principle.

2.3 A general principle of international law?

Determining whether or not the precautionary principle has become a general principle of customary international law has been a central issue to much academic debate. Whereas traditionally, most commentators have observed that precaution lacked the precision required to elevate status to legally binding general norm, post-Rio literature has tended to construe its widespread recognition as a sign of newfound prominence in the international arena. An examination of the literature confirms a marked shift to the acceptance of the precautionary principle as an emerging, if not fully-fledged, component of customary law.

However, as the following chapter points out, the argument that the precautionary principle has developed into general customary rule is erroneous in that it is based solely on the frequency with which the precautionary principle is cited, and is ignorant of the fact that the content of the principle is insufficiently normative to be described as a general norm. Bodansky, for example, observes that the ambiguity of the precautionary principle makes it impossible to adopt as a regulatory standard.⁵⁴ Von Moltke explains that the precautionary principles is situated at a 'meta-level' and thus requires clarification and operationalisation if it is to be considered a universally binding norm.⁵⁵ The position is compellingly summarised by Birnie and Boyle, who accurately point out that:-

"[d]espite its attractions, the great variety of interpretations given to the precautionary principle, and the novel and far-reaching effects of some applications suggest that it is not yet a principle of international law.

⁵⁴ Bodansky, D. (1991) 'The Precautionary Principle: Scientific Uncertainty and International Environmental Law', American Society of International Law, Annual Meeting, Washington D.C. 19 April 1991, (1991) 85 Proceedings of the American Society of International Law 413-417, at page 417. ⁵⁵ Von Moltke, K. (1996) at page 101.

Difficult questions concerning the point at which it becomes applicable to any given activity remain unanswered and seriously undermine its normative character and practical utility, although support for it does indicate a policy of greater prudence on the part of those states willing to accept it."⁵⁶

Reflecting these concerns, Cameron and Abouchar argue that at the international level there are three aspects of definitional ambiguity. First, ambiguity exists in relation to the threshold of harm required for application of the principle.⁵⁷ The Climate Change Convention and the Rio Declaration, for example, require a risk of 'serious of irreparable' damage. The Convention on Biological Diversity, on the other hand, demands 'significant' harm, whilst the OSPAR Convention insists on there being 'reasonable grounds for concern'. Second, the means of achieving a precautionary environmental protection are uncertain.⁵⁸ Whereas the Rio Declaration imposes an obligation to employ 'cost-effective measures', it fails to make elucidate the type and scale of pre-emptive action required. Third, it is unclear whether the precautionary principle should enforce the 'common but differentiated approach'⁵⁹ contained in the Rio Declaration. Principle 15 requires that participating States invoke the precautionary principle 'according to their capabilities', although other expressions of precaution require unqualified application.⁶⁰

The difficulty of ascertaining its prescriptive content is particularly evident in the judicial approach taken in relation to the principle. A selection of international cases, discussed below, illustrate how the courts' refusal to clarify its international status can be interpreted as a lacking consensus as to the meaning and application of precaution. Whilst the courts have often recognised precaution as an imperative means of environmental protection, and on occasion declared that the precautionary principle

⁵⁶ Birnie, P. W. and Boyle, A. E. International Law and the Environment (John Wiley & Sons; London; 1992) at page 98.

⁵⁷ Cameron, J. and Abouchar, J. (1996) at page 44.

⁵⁸ *Ibid.* at pages 44-5.

⁵⁹ *Ibid.* at page 45.

⁶⁰ See, for example, Convention for the Protection of the Marine Environment of the North-East Atlantic: "preventive measures are to be taken when there are reasonable grounds for concern"; see also, Bacon, L. 'Enforcement Mechanisms in International Wildlife Agreements and the United States: Wading Through the Murk' (1999) 12 *Geo. Int'l Envtl. L. Rev.* 331, at page 331: "uncertainties about the ability of a fish stock to sustain a harvest level must be resolved in favor of the fish."
may be considered a customary rule, they have so far been averse to making a definitive statement as to its status. It is perhaps unsurprising that, given the politically-charged nature of the disputes in which the concept of precaution has been called into question, the courts have declined to take a proactive role.

Contrary to the arguments submitted by Bodansky, Von Moltke, Birnie and Boyle, and Cameron and Abouchar, some commentators claim that there is evidence to suggest that the courts should regard the precautionary principle as having developed into a customary norm of international law. Sands, for example, notes that:-

"[t]he legal status of the precautionary principle is evolving. At a minimum, however, there is sufficient evidence of state practice to justify the conclusion that the principle, as elaborated in the Rio Declaration and the Climate Change and Biodiversity Conventions, has now received sufficiently broad support to allow a good argument to be made that it reflects a principle of customary law."⁶¹

Legal scholars have tended to argue that, despite the fact that there lacks international consensus as to its precise definition, it is possible to identify the conceptual core of the precautionary principle.⁶² The essence of all interpretations of the precautionary principle is that regulatory inaction is unjustified when the environmental risks posed by such inaction are (i) uncertain and (ii) non-negligible.⁶³ Arguably, this capacity to isolate its central tenets makes the precautionary principle "no less vague" than other principles of international law.⁶⁴ In defining the notion of 'public utility' in relation to expropriation and compensation in international law, Kissam and Leach observe that:-

"the fact that a concept lacks precise definition does not necessarily result in it becoming completely meaningless or without value. If, for example, an expropriation were submitted to an international tribunal for a

⁶¹ Sands, P. 'Principles of International Environmental Law: Volume 1: Frameworks, Standards and Implementation', in Sands, P. *et al* (eds) Principles of International Environmental Law: Volumes 1-4 (Manchester University Press; Manchester; 1995) at page 213.

⁶² See, for example, Cameron, J. and Abouchar, J. (1996) at page 37.

⁶³ Cameron, J. and Wade-Grey, W. (1992) at page 8.

⁶⁴ Cameron, J. and Abouchar, J. (1996) at page 46.

determination of the question as to whether the property expropriated was taken for reasons of public utility, the tribunal would not be prevented from resolving the issue merely because no ideally satisfactory definition of 'public utility' exists. An exact definition is neither possible nor necessary. Municipal tribunals throughout the world daily interpret and apply such seemingly amorphous concepts as 'good faith', 'reasonable man', 'due process', and the like, although it would be difficult to define these phrases with any absolute degree of finality."⁶⁵

Although the argument that other decision rules are just are poorly defined is a weak defence of the precautionary principle, it is perhaps *de minimus* verification that this lack of precise definition is not indicative of its futility. Regardless of its definitional ambiguity, it is possible to discern a broad philosophy of precaution, incorporating notions of prudence and pre-emption. Its poorly defined nature enables the concept of precaution to adopt an overarching position in environmental protection. However, in my opinion, its definitional deficit is at odds with any attempt to depict it as being sufficiently normative to become a customary rule.

This duality of the generality and flexibility of precautionary philosophy on the one hand, and its lack of prescriptive guidance on the other, is displayed by judicial attitudes to precaution. Despite its widespread recognition in the international arena, the argument that the precautionary principle is a legally binding norm has found somewhat limited judicial support in the international arena.⁶⁶ The following section illustrates that, notwithstanding their tendency to acknowledge precautionary ethos, the courts have been uneasy with the responsibility of determining the meaning and legal status of the precautionary principle. The upshot of the courts' failure to make any definitive statement is that the precautionary principle continues to lack in specificity and normative content, and as a result, has not yet become a legally binding mandate. Although Freestone claims that "discussions about whether the precautionary principle is a binding principle of international customary law have a

⁶⁵ Kissam, L. T. and Leach, E. K. 'Sovereign Expropriation of Property and Abrogation of Concession Contracts' (1959) 28 Fordham Law Review 177-214, at page 190.

⁶⁶ Bell, S. and McGillivray, D. (2000) at page 48. De Sadeleer makes a similar observation that international courts are renowned for their lack of enthusiasm to accept precautionary principle as legally binding, De Sadeleer, N. (2002) at page 22.

distinctly 1990s feel about them",⁶⁷ the debate will remain fierce for as long as there lacks common understanding as to when the precautionary principle is applicable, and what its application entails.

2.4 Examining the case law

According to Trouwborst, a broadly precautionary approach can be traced to the judgment of the ICJ in the *Corfu Channel* case⁶⁸ in 1949, which confirmed a general obligation on states to take preventive action where there is significant risk of transboundary damage from activities occurring within their borders.⁶⁹ However, the 'precautionary principle' was first *explicitly* cited during international judicial proceedings in the *Nuclear Tests Cases* of 1973-4,⁷⁰ which concerned a dispute over the French atmospheric nuclear testing at two atolls in the South Pacific. Australia and New Zealand claimed that, pursuant to a general obligation to prevent environmental harm, states planning to undertake activities with potentially negative environmental impact had to prove that those activities posed no risk. During ICJ pleadings, the Australian Advocate-General argued that, given the fact that any environmental degradation caused by atmospheric testing would be permanent, it was appropriate to adopt a precautionary approach:-

"Mr President, one of our primary legal propositions is that the deposit of radioactive fallout from the nuclear test infringes the inviolability of our territorial sovereignty. That proposition does not require Australia to establish the exact extent of the danger of these radioactive materials of which we are the unwilling target ... The processes of fallout deposit and

⁶⁷ Freestone, D. 'Caution of Precaution: A Rose By Any Other Name?' (1999) 10 Yearbook of International Environmental Law 25-32, at page 26.

⁶⁸ Corfu Channel Case – United Kingdom v. Albania (1949) ICJ Rep. 1, at page 1; are Trouwborst, A. Evolution and Status of the Precautionary Principle in International Law (Kluwer; The Hague; 2002) at page 158.

⁶⁹ Ibid.

⁷⁰ Australia v. France; New Zealand v. France (Interim Measures) (1973) ICJ Rep. 173; (Jurisdiction, Australia) (1974) ICJ Rep. 253; (Jurisdiction, New Zealand) (1974) ICJ Rep. 457.

the resulting uptake of radioactive material by the Australian people are irreversible; the legal injury is irreparable."⁷¹

In this particular instance, the ICJ did not make ruling because France announced that it would not carry out any further testing. However, twenty years later, France embarked upon a new scheme of underground nuclear testing. Unsurprisingly, Australia, New Zealand and other Pacific states attempted to reopen the case. In August 1995, New Zealand lodged 'Request for an Examination of the Situation',⁷² claiming that, in accordance with the precautionary principle, France was under an obligation to provide evidence before embarking upon nuclear testing that such testing would not introduce radioactive material to the environment.⁷³

The French government retaliated, claiming that it was under no *legal* obligation to prevent environmental degradation caused by radioactive contamination since the international status of the precautionary principle was "tout à fait incertain"⁷⁴, and that, in any event, it had already been complied with.⁷⁵

Unfortunately, the ICJ was prevented from handing down judgment on the precautionary principle and other substantial issues,⁷⁶ and New Zealand's request was dismissed without recourse to a discussion of the merits. The three dissenting judges, however, concluded that New Zealand had made a *prima facie* case, and their

⁷¹ per Senator Murphy; ICJ Pleadings, Oral Arguments, Documents: Nuclear Test Cases, Vol. I, at page 43.

⁷² ICJ Order, 22 September 1995, Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case; in (1995) ICJ Rep. 288.

⁷³ *Ibid.* at page 290.

⁷⁴ 6 Yearbook of International Environmental Law (1995) 536, which cites judgment New Zealand v. France, pages 71-72 and 75.

⁷⁵ Ibid.

⁷⁶ The Court noted that:- "in analysing [the ICJ] Judgment of 1974, it reached the conclusion that that Judgment dealt exclusively with atmospheric nuclear tests; that consequently, it is not possible for the Court now to take into consideration questions relating to underground nuclear tests; and that the Court cannot, therefore, take account of the arguments derived by New Zealand, on the one hand from the conditions in which France has conducted underground nuclear tests since 1974, and on the other from the development of international law in recent decades - and particularly the conclusion, on 25 November 1986, of the Noumea Convention - any more than of the arguments derived by France from the conduct of the New Zealand Government since 1974." For full text of Request for an Examination of the Situation with Paragraph 63 of the Court's Judgment of 20 December 1974 in the France) Nuclear Tests (New Zealand v. see http://www.icjcij.org/icjwww/icases/inzfr/inzfr summaries/inzfr isummary 19950922.htm, accessed January 2005.

comments may be used to indicate judicial perception of the status of the precautionary principle in international environmental law.

Judge Koroma did not go beyond acknowledging the argument made by New Zealand regarding the precautionary principle, merely stating that "there is *probably* a duty not to cause gross or serious damage which can reasonably be avoided."⁷⁷ Judge *Ad Hoc* Palmer, on the other hand, suggested that the precautionary principle *might* be described as "a principle of customary international law relating to the environment."⁷⁸

Although the international courts have suggested that the principle should be treated as more than merely a guiding concept,⁷⁹ they have avoided definitively concluding that it has evolved into a customary rule of international law. It is reasonable to suggest that this judicial apprehension is reflective of lacking consensus as to the precise meaning and application of the precautionary principle. Whilst the courts have acknowledged precaution as a broad philosophy of environmental protection, they have avoided defining the precautionary principle, arguably because demarcating its operation presents too challenging a task beyond the demands of arbitration.

This thesis does not seek to resolve the debate surrounding the legal status of precaution, although on the evidence provided, it is my opinion that it has not yet developed into an international customary norm – although it is likely that deliberations of this nature will continue. The purpose of this chapter has been to introduce the argument that the definitional deficit of the precautionary principle manifests in its divergent interpretation and disagreement about its normative content. My studies of the precautionary principle began with in-depth consideration of its lacking definition, and on discovering its contentious nature, it has become clear that

⁷⁷ Dissenting Opinion of Judge Koroma on the 1995 Nuclear Tests Cases, ICJ Order, 22 September 1995, Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case; in (1995) ICJ Rep. 288, at 363-380, emphasis added.

⁷⁸ Dissenting Opinion of Judge Ad Hoc Palmer, ICJ Order, 22 September 1995, Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 December 1974 in the Nuclear Tests (New Zealand v. France) Case; in (1995) ICJ Rep. 288, 381-421, at page 412.

⁷⁹See, for example, Case Concerning the Gabcikovo-Nagymaros Project (*Hungary v. Slovakia*) 25 September 1997, (1998) 37 *ILM* 162; Separate (dissenting) Opinion of Judge Weeramantry <u>http://www.icj-cij.org/icjwww/idocket/ihs/ihsjudgement/ihs_ijudgment_970925_weeraman.htm</u>, accessed July 2004 at paragraph A.

legal judgments provide a key insight into the evolution of its scope and application. The most illustrious judgment at the international level – the WTO Beef Hormones Dispute - is discussed in the following chapter. Although I initially approached this case wanting to ascertain the international status of the precautionary principle, my interest quickly shifted to defining the relationship between precaution and risk assessment. This was because, despite the fact that the Beef Hormones Dispute is often cited as the pivotal case in determining the legal status of precaution, both the WTO Dispute Resolution Panel and the Appellate Body judgments fail to explicitly add substance to the continuing debate. The most interesting aspect of this case, from my perspective, is the way in which the role of scientific risk assessment in determining the application of precaution was perceived by the Courts. The next chapter discusses, in some detail, the relationship between risk assessment and precaution from US and EC standpoints - which build upon the transatlantic divide observed in UN Preparatory Committee meetings. In doing so, it introduces more abstract topics, such as the definition of the concept of risk and the utility of scientific foresight.

Chapter Three

The Beef Hormones Dispute: an analysis of the role of precaution

3.0 Introduction

The debate over the international status of the precautionary principle climaxed in 1998 when the WTO Dispute Resolution Body was charged with the task of determining whether an EC ban on the import of hormone-treated bovine violated the trade harmonisation provisions of the SPS Agreement. Although the Reports of both the WTO Dispute Resolution Panel and the Appellate Body carefully avoided the question of its international status, they are useful because they highlight the irresolvable conflict between differing interpretations of the precautionary principle and its reliance on scientific risk assessment. The objective here is to provide a description of proceedings together with an analysis of broader themes such as judicial interpretations of 'science' and 'risk', and the extent to which scientific assessment informs a precautionary response to uncertainty.

However, before turning to examine the WTO Beef Hormones Dispute in more detail, it is worth placing the EC's stance in its historical context, with particular reference to a case brought before the ECJ in 1988, *Re Agricultural Hormones*. It is important to note that the approach taken by the EC at the WTO in 1998 is reflective of the conduct of EC institutions in the early and mid 1980s, and for that reason, it is necessary to pay due attention to proceedings leading up to the WTO litigation.

3.1 Background

On 31 July 1981, the EC Council of Ministers adopted Directive 81/602 by qualified majority on the basis of Article 43 EC Treaty,¹ prohibiting 'certain substances having

¹ Now Article 37 EC Treaty

a hormonal action and of any substances having thyrostatic action.² Specific substances contained in Article 2 of the Directive were not to be administered to farm animals, although Article 4 provided that Member States could authorise the administration of certain substances for therapeutic (and similar) purposes. In order to ascertain the safety of the use substances under Article 4, Article 5 of the Directive required that the Council, acting unanimously on the basis of a proposal from the Commission, should decide 'as soon as possible' on the administration of five anabolic agents for fattening purposes. Those substances were oestradiol 17- β , progesterone, testosterone, trenbolone and zeranol. In accordance with Article 8, the Commission set up a scientific group to examine their effects. The Scientific Group on Anabolic Agents in Animal Production³ was chaired by Professor Lamming (and known as the 'Lamming Group'). It issued an interim report on 22 September 1982.

This Report explained that the use of such growth promoters in farm animals resulted in accelerated conversion of foodstuff and protein deposition.⁴ It also noted that the hormones in question already occurred naturally in farm animals, and thus "have to be considered as inevitable constituents of food from animal origin."⁵ Oestradiol-17 β , testosterone and progesterone were present naturally in milk in varying quantities depending on the physiological condition of the animal,⁶ and it was agreed that they had an inconsequential impact on animal health. The Report observed that:-

"[u]nder appropriate conditions the treatment of animals with exogenous natural steroids results in residues in edible tissues which are orders of magnitude lower than those that can occur naturally in mature males, females and pregnant females. Therefore in practice *no quantitative differences* have been observed between treated and untreated animals when the recommended conditions of use were observed. Levels in

 $^{^2}$ Directive 81/602, OJ 1981 L222/32, amended by Directive 85/358, extended in 1988 (Directives 88/146 OJ 1988 L70/16 and 88/299 OJ 1988 L128/36) and consolidated by Directive 96/22 OJ 1996 L125/3.

³ EU Commission, Report of the Scientific Group on Anabolic Agents in Animal Production (EU Commission; Brussels; 1982)

⁴ *Ibid*. at paragraph 1.

⁵ *Ibid.* at paragraph 3.

⁶ Ibid.

treated and untreated calves are if the order of 0.1µg testosterone/kg and 0.03µg natural oestrogens/kg edible tissue."⁷

Regarding potential risks created by the human consumption of meat treated with exogenous anabolic hormones, the Report found that the quantity of hormones used was "toxicologically negligible".⁸ Furthermore, it held that, provided the agents were properly used, the liver and placenta actually formed tissue barriers to prevent adverse toxicological effects of the consumption of anabolic hormones.⁹

On the basis of this evidence, the Lamming Group was able to conclude that the use of oestradiol-17 β , testosterone and progesterone did not present any harmful effects to consumer health when used under appropriate conditions as growth promoters in farm animals.¹⁰ This opinion was subsequently supported by the EC Scientific Veterinary Committee,¹¹ the EC Scientific Committee for Animal Nutrition,¹² and the EC Scientific Committee for Food.¹³ However, with regard to the administration of trenbolone and zeranol, the Lamming Group concluded that it was necessary to conduct further scientific studies before determining their safety.¹⁴

In the light of the scientific advice, the Commission published a proposal¹⁵ for a Council Directive amending Directive 81/602/EEC, calling for the controlled use of oestradiol-17ß, testosterone, and progesterone for fattening purposes. However, following consultations with the Economic and Social Committee¹⁶ and the European Parliament,¹⁷ the proposal was rejected. In essence, both institutions considered that the scientific evidence upon which the proposal was based was inadequate.¹⁸ This is, to say the least, an intriguing position given the scientific position that oestradiol-178,

⁷ *Ibid.* emphasis added.

⁸ Ibid.

⁹ Ibid.

¹⁰ *Ibid.* Conclusions and Recommendations, at paragraph 5.1.

¹¹ Opinion of the Scientific Veterinary Committee, expressed 9 November 1982, paragraph 2.

¹² Opinion of the Scientific Committee on Animal Nutrition, expressed 17 November 1982, at paragraph 2. ¹³ Opinion of the Scientific Committee for Food, expressed 4 February 1983, III/197/83-EN, see

Conclusions and Recommendations.

¹⁴ EU Commission (1982) at paragraphs 5.2 and 5.3.

¹⁵ COM(84)295 Final.

¹⁶ See Economic and Social Committee Opinion [1985] OJ C44/14.

¹⁷ See European Parliament Resolution [1985] OJ C288/158.

¹⁸ See Economic and Social Committee Opinion [1985] at paragraph 10; European Parliament Rsolution [1985] at paragraph 6.

testosterone, and progesterone, used in a controlled and appropriate manner, posed only a *negligible* risk to animal and human health.¹⁹ The Economic and Social Committee, in particular, considered that the evidence presented in the Lamming Report had failed to establish the safety of the three anabolic agents on the basis of "sound experience covering, inter alia, conditions of use",²⁰ and thus could not be relied upon as irrefutable proof that their use would not jeopardise consumer protection. Unsurprisingly, in 1987 the Lamming Group was disbanded, and its findings were published independently of the EC.²¹

Prima facie, the rationale underlying the outright rejection by the Economic and Social Committee and the European Parliament of the authorised use of those three substances is unclear. A closer examination of the Opinions submitted those two institutions, however, suggests that the direct protection of animal and consumer safety was not the principal focus of their concern. For instance, the Economic and Social Committee was eager to point to the fact that "[t]he representatives of consumers and workers have for a long time been unequivocally opposed to the use of anabolics in livestock fattening."²² Similarly, the European Parliament highlighted that "the resultant uncertainty over the safety of these substances has had an adverse effect on consumer confidence",²³ and added that the overproduction of meat and meat products as a consequence of the use of anabolic agents added considerably to the costs of the Common Agricultural Policy.²⁴ It is evident, therefore, that both the Economic and Social Committee and the European Parliament had far wider terms of reference than the Lamming Group. Whereas the Lamming Group adopted a narrowly scientific sphere of enquiry, the Economic and Social Committee and the European Parliament took into account a markedly broader range of factors, making their risk assessment a political rather than purely scientific exercise. It was thus

¹⁹ See Report of the Scientific Veterinary Committee, The Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production (Directorate-General for Agriculture; Commission of the European Communities; Luxembourg; 1984) Document EUR8913. ²⁰ Economic and Social Committee Opinion [1985] at paragraph 10.

²¹ Bridges, J. W. and Bridges, O. 'Hormones as Growth Promoters: The Precautionary Principle or a Political Risk Assessment?', in Harremoës, P. (ed) et al, The Precautionary Principle: Late Lessons From Early Warnings (Earthscan Publications Ltd; London; 2002) chapter 14, at page 163; see also Lamming, G. E. et al 'Scientific Report on Anabolic Agents in Animal Production' (1987) 121 The Veterinary Record 389-392.

²² Economic and Social Committee Opinion [1985] at paragraph 9.

²³ European Parliament Resolution [1985] at paragraph J.

²⁴ *Ibid.* see Introduction.

inevitable that their position on the administration of anabolic agents would differ from that of the Lamming Group.

The Commission proposal was amended accordingly,²⁵ resulting in the adoption of Directive 85/649 on 31 Dec 1985 prohibiting the use of all substances for growth promotion purposes, permitting authorised use only for therapeutic purposes. Article 2 of Directive 85/649 stipulated that States derogating from Article 2 of Directive 81/602 were only permitted to do so in accordance with Article 4 of Directive 81/602. Article 5 of Directive 85/649 required that Member States ensured that no farm animals (or meat from such animals) to which certain substances have been administered were dispatched to other Member States. Article 6 obliged Member States to prohibit the import of farm animals (or meat animals from such animals) to which certain substances have been administered.

3.1.1 Re Agricultural Hormones²⁶

The UK, supported by Denmark, made an application to the ECJ for a declaration that Directive 85/649 was void, claiming that the Directive should have been based on Article 100 EC Treaty²⁷ which required first, a unanimous vote for measures relating to the approximation of legislation and second, the consultation of the European Parliament and the Economic and Social Committee. The UK submitted that the Council's reliance on Article 43 was insufficient because the scope of the Directive in question extended beyond securing the aims of the common agricultural policy to the approximation of legislation in relation to the safeguarding to the interests and health of consumers.²⁸

The Council did not deny that part of the Directive dealt with the approximation of national laws in respect of the protection of public health, but it argued that this did

²⁵ [1985] OJ C313/4.
²⁶ [1988] 2 C.M.L.R 543.

²⁷ Now Article 94

²⁸ Ibid. at 551

not cause it to fall outside the scope of the common agricultural policy, meaning that Article 43 provided a sufficient legal basis.²⁹

The Court held that when the Directive was read in the light of Article 39 EC Treaty,³⁰ which established the objectives of the common agricultural policy,³¹ it became clear that Article 39 allowed far-reaching regulation of the markets, including approximation measures.³² Accordingly, efforts to achieve the objectives of the common agricultural policy "cannot disregard requirements relating to the public interest such as the protection of consumers or the protection of health"³³ As a result, Article 43 was considered to be the appropriate legal basis since the Directive was aimed primarily at achieving common agricultural objectives, and common agricultural policies were deemed to encompasses harmonisation measures. Thus recourse to Article 100 was held to be unnecessary.³⁴

Incidentally, Directive 85/649/EEC was declared void on procedural grounds, for its failing to comply with Article 6(1) of the Council's Rules of Procedure, constituting an infringement of an essential procedural requirement within the meaning of Article 173(1) of the Treaty. However, in order to fully understand the approach taken by the EC in 1998 at the WTO, it is important to give some consideration to the arguments submitted by the UK and the Council in relation to the Lamming Report, and to the judgment passed down by the ECJ.

Essentially, the UK claimed that the Council was under an obligation, pursuant to Article 8 of Directive85/649, to consider the Lamming Report, and that, in the light of its findings, there was no scientific evidence justifying the ban on the use of hormones. To recap, Article 8 stipulated that:-

"[n]ot later than 1 July 1984, the Commission shall submit to the Council a report on the experience acquired and scientific developments,

²⁹ *Ibid*. at page 569, paragraph 5.

³⁰ Now Article 33

³¹ *Ibid.* at pages 552-3.

³² *Ibid.* at page 553.

³³ *Ibid.* at page 570, paragraph 12.

³⁴ *Ibid*. at page at 553.

accompanied, if necessary, by proposals which take these developments into account."

The UK Government argued that Article 8 required that the Council take into account the fact that the Lamming Group had concluded that oestradiol-17 β , testosterone, and progesterone did *not* present any risk to animal and human safety, and that the Directive should reflect these findings. However, the ECJ was of the opinion that that the scientific report was intended for the Commission, and that the Commission, *not* the Council, was under a duty to consider it when drafting proposal for the contested Directive.³⁵ Furthermore, given that the Lamming Report dealt only with three of the five hormones in question, it did not unequivocally support the UK's claim that consumer health was not endangered.³⁶

The most significant aspect of the judgment, however, lies in the breadth of the Court's attitude to issues of consumer safety. Perhaps the most telling statement made by the Court was that "there was really no reason to examine the health problem in particular".³⁷ Notably, the approach taken by the Court extended beyond a narrowly scientific consideration of potential risks to health – evident in its conclusion that it was 'certain' that the Lamming Report "did not have to be considered in depth".³⁸ Instead of restricting its focus solely to matters of health, the Court extended its analysis to include the notion of *public interest* which was deemed to encompass *more* than consumer health.³⁹ The words of Advocate General Lenz are useful in rationalising this approach. For example, Lenz recognised that:-

"the predominant concern of the Commission, and thereafter of the Council as well, was not so much the safeguarding of the health of consumers (a problem which the Scientific Group considered above all) but to *take into account the interests of consumers in general*."⁴⁰

³⁵ *Ibid.* at page 558.

³⁶ *Ibid*. at page 567.

³⁷ *Ibid.* at page 558, emphasis added.

³⁸ *Ibid.* at page 567.

³⁹ *Ibid*. at page 543

⁴⁰ Ibid. at page 558, emphasis added.

On closer examination of the judgment, it transpires that 'the interests of consumers in general' are more directly associated with economic integration than with maintaining consumer health protection. This is evident in the Court's assertion that the contested Directive was primarily "a measure of economic policy in the agricultural sphere",⁴¹ and one which was necessary for the proper functioning of the Common Market.⁴² Lenz interpreted this as evidence that the main concern was establishing equal conditions of livestock fattening and upholding the objectives of unimpeded intra-Community trade free from distortions of competition.⁴³ It is worth pointing out that this issue was raised in a Resolution of the European Parliament,⁴⁴ which recognised that the ban on hormones used for fattening purposes would inevitably affect trade with third-country suppliers of meat products. In considering whether third countries were likely to be aggrieved, Lenz questioned "whether this is really a genuine danger or just an unsubstantiated fear".⁴⁵ Without doubt, the approach adopted by the Council and the ECJ in this case, and subsequently by the EC at the WTO in 1998, suggests that it perceived the threat as a genuine danger.

The proceedings of *Re Agricultural Hormones* can be regarded as setting the scene for the EC/US WTO Dispute. The interpretation of risk assessment as an analysis of factors beyond scientific risk quantification, encompassing more general consumer interests such as the objectives of the single market and the maintenance of consumer confidence, shifts the focus of risk assessment from science to politics. It is upon this political basis that the EC rekindled the hormone debate in 1998 when it was required to defend a measure prohibiting the administration of anabolic agents before the WTO Dispute Settlement Body. In doing so, the EC appeared to construe the concept of risk assessment in a broad manner, reflecting the response of the Court in *Re Agricultural Hormones*. Although the EC only made explicit reference to the scientific nature of its assessment, it is implicit that the adoption of a Directive in 1998 was motivated by factors other than scientific findings.

⁴¹ *Ibid.* at 555.

⁴² *Ibid*.

⁴³ *Ibid.* at page 557.
⁴⁴ [1985] OJ C288/158.

⁴⁵ Re Agricultural Hormones [1988] 2 C.M.L.R. 543, at page 568.

WTO Beef Hormones Dispute⁴⁶ <u>3.2</u>

In March 1988, proposals for the prohibition of anabolic agents were re-introduced by the Commission and adopted by the Council in Directive 88/146. In September that year, and in an attempt to avoid accusations of lacking scientific evidence in support of the measure, the European Parliament established the Committee of Enquiry into the Problem of Quality in the Meat Sector. The Committee reported (in the 'Pimenta Report') that the ban of hormonal substances for purposes other than therapeutic should be maintained.

Under the 1979 Tokyo Round of General Agreement on Technical Barriers to Trade,⁴⁷ the US sought to establish a 'technical experts group' in effort to illustrate that the EC ban could not be scientifically justified. The EC blocked the request,⁴⁸ and on 27 December 1988 the US retaliated by announcing the imposition of a prohibitive one hundred per cent tariff on a number of EC exports to the US, including canned tomatoes, fruit juices, instant coffee, and low alcohol drinks, to take effect from 1 January 1989.⁴⁹ On 26 January 1996, the US requested consultations with the EC regarding its prohibition,⁵⁰ and on 2 February 1997 requests were made by Australia⁵¹ and New Zealand,⁵² followed by Canada⁵³ on 8 February, to join the consultation. The requests were accepted by the EC on 19 March 1997.⁵⁴ Joint consultations took place on 27 March, but the parties failed to reach an agreement. A

⁵² WT/DS26/2. ⁵³ WT/DS26/4.

⁴⁶ EC-Measures Concerning Meat and Meat Products (Hormones), Panel Reports: Case WT/DS26/R/USA, 18 August 1997; Case WT/DS48/R/CAN, 18 August 1997; Appellate Body Report: WT/DS26/AB/R and WT/DS48/AB/R, 16 January 1998.

⁴⁷ Following from this, a 'Standards Code' was adopted. This has since been replaced by the Agreement on Technical Barriers to Trade (TBT) arising out of the Uruguay Round Agreements, to which all WTO Members are party.

⁴⁸ Winham, G. R. 'International Regime Conflict in Trade and Environment: the Biosafety Protocol and the WTO' (2003) 2(2) World Trade Review 131-155, at page 136.

⁴⁹ duties amounting to US\$93 million per annum, although duties were withdrawn in 1996 for being incompatible with WTO provisions. See Bridges, J. W. and Bridges, O. (2002) at page 167.

⁵⁰ See WT/DS26/1. The request made by the US was brought pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU); Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement); Article 14 of the Agreement on Technical Barriers to Trade (TBT Agreement); Article 19 of the Agreement on Agriculture; and Article XXII of the General Agreement on Tariffs and Trade 1994 (GATT).

WT/DS26/3.

⁵⁴ WT/DS26/5.

month later, the US called for the WTO Dispute Settlement Body to set up a panel to resolve the issue.⁵⁵

<u>3.2.1 WTO Framework and the SPS Agreement</u>

The World Trade Organisation was established by the Final Act of the Uruguay Round of Negotiations,⁵⁶ which was adopted in Marrakesh on 15 April 1994, and came into effect on 1 January 1995. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), an important constituent of the makeup of the WTO, combines the non-discriminatory sentiments⁵⁷ and concern for food safety⁵⁸ of the GATT 1947, and built upon food safety standards developed by the Codex Alimentarius Commission.⁵⁹ Essentially, the SPS Agreement prohibits the implementation of unjustified sanitary and phytosanitary measures for the purpose of trade protection. Although its underlying objective is the harmonisation of international standards of trade, it also aims simultaneously to preserve the right of parties to the agreement to establish the level of health protection it considers appropriate, except when SPS measures adopted present an unnecessary barrier to international trade. Accordingly, Members are obliged to ensure that measures are "not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members ... or a disguised restriction on international trade".⁶⁰ Although Members have the right to take sanitary or phytosanitary measures 'necessary' for the protection of human, animal or plant life,⁶¹ they can be applied 'only to the extent necessary' to achieve those objectives.⁶² Measures adopted for sanitary of phytosanitary purposes must be based on sufficient scientific evidence,⁶³ except where scientific knowledge is inadequate - in which case Members are

⁵⁵ WT/DS26/6; pursuant to Article 11 of the SPS Agreement; Article 14 of the TBT Agreement; Article 19 of the Agreement on Agriculture; Article XXIII:2 of the GATT; and Article 6 of the DSU.

 ⁵⁶ See the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations.
 ⁵⁷ in particular GATT Article I (Most Favoured Nation Treatment) and Article III (National Treatment)

⁵⁸ GATT Article XX(b), which states that "nothing in this Agreement shall ... prevent the adoption ... of measures ... necessary to protect human, animal or plant life or health.".

⁵⁹ A subsidiary body of FAO and the WHO.

⁶⁰ SPS Agreement Article 2.3.

⁶¹ *Ibid.* Article 2(1).

⁶² *Ibid.* Article 2(2).

⁶³ Ibid.

required to adopt *provisional* measures on the basis of 'available pertinent information'.⁶⁴

In the course of the Uruguay Round negotiations, which ended in 1993, the EC sought to explicitly incorporate the precautionary principle in SPS Agreement, but yielded to US pressure to require scientific risk assessment in the face of uncertain hazards.⁶⁵ Consequently, the SPS Agreement relies on scientific standards of proof, and makes explicit reference to concepts of scientific certainty⁶⁶ and scientific justification.⁶⁷

<u>3.2.2 Proceedings</u>

The WTO Panel held that the EC ban violated three provisions of the SPS Agreement. First, it found that the EC prohibition was inconsistent with the obligation pursuant to Article 5.5 to ensure that SPS measures are non-discriminatory, which requires the avoidance of arbitrary or unjustifiable distinctions in the level of protection resulting in discrimination or disguised restrictions on international trade. Second, given that the EC ban did not adopt the Codex Alimentarius Standards that deemed the use of anabolic hormones to be safe, it did not satisfy the harmonization requirement of Article 3. Third, the Panel found that not only had EC failed to conduct a scientific risk assessment in a satisfactory manner, but had also failed to demonstrate that its prohibition was 'based on' an appropriate risk assessment, which constituted an infringement of Article 5.1 of the SPS Agreement. In relation to this last point, the Panel Report suggests that its decision could be partly attributed to the fact that the preamble to the contested EC Directive did not explicitly refer to scientific evidence.⁶⁸ To base its decision on the absence of scientific substantiation in the Directive preamble is questionable. Macmillan rightly points out that "[t]his is the sort of ruling that should make one glad that an Appellate Body exists."⁶⁹

⁶⁴ *Ibid.* Article 5(7).

⁶⁵ Winham, G. R. (2003) at pages 134-135.

⁶⁶ SPS Agreement Article 2(2).

⁶⁷ *Ibid.* Article 3(3); Article 12(3).

⁶⁸ Panel Report, at paragraph 8.122

⁶⁹ Macmillan, F. WTO and the Environment (Sweet & Maxwell; London; 2001) at page 150.

The EC appealed the Panel's decision, and the Appellate Body rejected two of the three grounds upon which it was based. First, the Appellate Body rejected the argument that the EC prohibition infringed Article 5.5 argument, concluding that the contested measure could not be held to be discriminatory because the rationale was not trade-related. Secondly, the Appellate Body rejected the argument that the EC prohibition was inconsistent with Article 3, concluding that the Article 3 requirement that measures be based on international standards did not mean that SPS measures had to conform to those particular Codex standards.

However, although the Appellate Body upheld the Panel's third argument that the ban infringed Article 5.1, it took a slightly different view. It concluded that, although a Member implementing an SPS measure was under no procedural obligation to carry out a risk assessment, it was required to rely upon a risk assessment irrespective of by whom it was conducted.⁷⁰ It is on this basis that the Court concluded that the EC prohibition was invalid.⁷¹

Arguably, this was a surprisingly narrow verdict. In its ruling, the Appellate Body made an attempt to broaden the meaning of conventionally-scientific risk assessment. First, it extended the scope of risk assessment, beyond that espoused by the Panel, allowing non-scientific factors to be taken into account. It concluded that the risk to be evaluated in risk assessment under Article 5.1 was:-

"not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."⁷²

Second, the Appellate Body held that Article 5.1 did not require that an SPS measure accord with the consensus of scientific community, stating that the purpose of risk assessment was not to reach a 'monolithic conclusion' that coincided with the

⁷⁰ Appellate Body Report, at paragraphs 189-191.

⁷¹ *Ibid.* at paragraph 208.

⁷² *Ibid.* at paragraph 187.

majority opinion.⁷³ A divergence, according to the Appellate Body, indicated a roughly equal balance of scientific opinion.⁷⁴

Yet, in spite of seemingly liberal approach, the Appellate Body concluded that there was no rational relationship between EC ban and the risk assessment required under Article 5.1 – primarily because the risk assessment relied upon was too vague, failing to give a sufficiently detailed account of specific risk posed. The Appellate Body identified the risk as being "the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes."⁷⁵ However, scientific studies cited by the EC lacked the requisite specificity, analysing the carcinogenic potential of exogenous hormones in general, as opposed to hormones directed at promoting animal growth.

As well as violating Article 5.1, it was also held that the imprecision with which the EC risk assessment was conducted breached paragraph 4 of Annex A to the SPS Agreement which required "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs." Adopting a narrow interpretation of the word 'base', the Appellate Body held that the EC measure was not based on risk assessment as defined by paragraph 4, Annex A.

With regard to the precautionary principle, the EC claimed that Articles 5.1 and 5.2 should be read in accordance to the precautionary principle. Both the Panel and the Appellate Body were agnostic to the question of whether the precautionary principle existed, and avoided clarifying its status, if any, in international environmental law. The Appellate Body noted that:-

"[t]he status of the precautionary principle in international law continues to be the subject of debate amongst academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as

⁷³ Ibid. at paragraph 194.
⁷⁴ Ibid.

⁷⁵ Ibid. at paragraph 200.

having crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation."⁷⁶

It is interesting that the Appellate Body considered that it was 'unnecessary' and 'imprudent' to make a definitive statement as to its international status, particularly in the light of the preamble to the Agreement Establishing the WTO which requires the "optimal use of the world's resources in accordance with the objective of sustainable development". Given that sustainable development is deemed to be a central tenet of the WTO, and that the precautionary principle is frequently considered by other international agreements to be an essential element of sustainable development, the Appellate Body's silence is surprising.

Instead of determining its status, the Appellate Body opted to outline four principles governing the relationship between the SPS Agreement and the precautionary principle.⁷⁷ First, the implementation of the precautionary principle does not justify measures otherwise inconsistent with the Agreement. Secondly, Appellate Body claimed that the precautionary principle is already reflected in Article 5.7, which operated where relevant scientific evidence was insufficient. In such circumstances, a Member is permitted to adopt sanitary or phytosanitary measures on the basis of 'available pertinent information', whilst continually seeking to obtain the additional information necessary for a more objective risk assessment and to review the measures accordingly within a reasonable period of time. According to the Appellate Body, there was no need to assume that Article 5.7 exhausted the relevance of the

⁷⁶ *Ibid. at* paragraph 123.

⁷⁷ *Ibid. at* paragraph 124.

precautionary principle⁷⁸ because it was also reflected in Article 3.3 and the sixth paragraph of the preamble, enabling Members to establish their own levels of sanitary protection, even if they were more cautious than those implied by existing international standards.

Thirdly, in determining whether 'sufficient scientific evidence' required by Article 2.2 existed, a panel was obliged to bear in mind that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-threatening, damage to human health are concerned."⁷⁹

Finally, the Appellate Body held that the precautionary principle did not displace the principles of treaty interpretation. From this perspective, the precautionary principle could not exonerate the EC from its failure to comply with Articles 5.1 and 5.2 of the SPS Agreement.⁸⁰

Overall, the Appellate Body can be described as having given "short shrift to the precautionary principle".⁸¹ Although it did take steps towards clarifying the relationship between precaution and the SPS Agreement, portraying the precautionary principle as a scientific tool of risk assessment, its finding that it would be 'imprudent' to determine its legal status has maintained the elusiveness of precaution. In this instance, the WTO renounced the opportunity of making an authoritative statement on the standing of the precautionary principle in customary international law. This judicial timidity suggests that the problem of defining precaution is more profound than a simple elucidation of terms. Ambiguity is present in its conceptual core.

Ultimately, the Appellate Body held that the EC ban on the import of beef from any source containing artificially administered growth hormones violated the SPS Agreement. Interestingly, the EC measure was found to breach the Agreement despite the fact that it was not shown to restrict international trade – the point being

⁷⁸ Ibid.

⁷⁹ *Ibid*.

⁸⁰ *Ibid.*

⁸¹ Winham, G. R. (2003) at page 140.

that the EC prohibition was not 'based on' risk assessment,⁸² and that the scientific evidence presented neither focused on nor addressed the particular kind of risk at stake.

• <u>3.3.3 Case analysis</u>

Although it has received little academic criticism,⁸³ the Appellate Body ruling is problematic for three reasons. First, given that there is compelling evidence that oestradiol-17 β poses a risk to human health,⁸⁴ it is unfortunate that the EC's initial precautionary prohibition was so heavily criticised. Although hindsight is undoubtedly beneficial, it is arguable that Article 3.3 of the SPS Agreement permitted the adoption of the prohibition. Article 3.3 states that:-

"Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved international by measures based on standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement."

⁸² SPS Agreement Article 5.1; See Appellate Body Report at paragraph 193.

⁸³ Quick, R. and Bluthner, A. 'Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case' (1999) 2 Journal of International Economic Law 603-639, at page 636; Winham, G. R. (2003) at page 140.

⁸⁴ In the aftermath of the *WTO Beef Hormones Dispute*, the EC Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) conducted an additional risk assessment, and concluded that oestradiol 17 β must be considered a complete carcinogen. The Committee was unable to provide a definitive opinion on five other hormones in question. This formed the basis of Council Directive 2003/74/EC which amended Directive 96/22/EC. Directive 2003/74 prohibited the use of oestradiol-17 β in farm animals, and provisionally banned the other five hormones until further scientific evidence became available.

Paragraph 5 of Annex A defines the 'appropriate' level of sanitary or phytosanitary protection as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." On the basis of Article 3.3 and Annex A, paragraph 5, it is reasonable to conclude that the EC should have been entitled to determine levels of environmental protection beyond those stipulated by the SPS Agreement. Following the WTO ruling, and in response to the Appellate Body's concern about its failure to produce a sufficiently comprehensive and detailed risk assessment, the European Commission launched a series of 17 specific scientific studies to determine whether the threat posed by the contested hormones was indeed genuine. Late in 1998, an independent body - the Scientific Committee of Veterinary Measures Relating to Public Health (SCVPH) - was established to conduct an assessment of the risk to human health arising from the administration of six hormones (oestradiol-17ß, testosterone, progesterone, trenbolone, zeranol, and MGA) for growth promotion purposes. Of the nine specialists making up the SCVPH, four scientists were from the US. The working group met several times, before delivering its opinion on 30 April 1999. It concluded that possible endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic, and carcinogenic risks to consumers had been identified with differing levels of conclusive evidence for each of the six hormones. In particular, the Committee found that, although it was impossible to quantify the risk with any degree of certainty, there was a substantial body of evidence suggesting that oestradiol- 17β was tumour-initiating and tumour-promoting. With regards to the other five anabolic agents, the Committee considered that no safe threshold levels could be established, yet despite being unable to quantify the risk associated with their administration, it was possible to estimate the risk in qualitative terms. Although in April 2000 the SCVPH re-examined the risk in the light of new scientific information, it did not revise its 1999 opinion. Arguably, against the backdrop of Article 3.3, the EC should have been permitted to undertake a separate scientific investigation into the growth promoting agents, and adopt a higher level of consumer protection on the basis of evidence found.

Secondly, the Appellate Body concluded that the studies relied upon by the EC lacked the requisite level of precision and detail.⁸⁵ The level of specificity required in a risk assessment was set out in paragraph 4 of Annex A to the SPS Agreement, which defined risk assessment as "the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". The Appellate Body considered that this provision was sufficient proof that the EC was compelled to rely on specific and comprehensive scientific evidence. For this reason, scientific studies relating to carcinogenicity of anabolic agents in general were deemed to violate the paragraph 4 proviso.⁸⁶ Yet, paragraph 4 is silent as to whether there had to be an exact correlation between the way in which those agents were used during scientific experiment and the uses proposed in the contested regulation. It can be argued that the specificity requirement had no textual footing in the SPS Agreement. Even the Panel concluded that several of the EC scientific studies relating to the carcinogenic potential of entire categories of hormones met the minimum requirements of a risk assessment.⁸⁷ As Wirth rightly points out, the specificity requirement in paragraph 4 is not 'blindingly obvious'.⁸⁸

The finding that the EC failed to satisfy paragraph 4 obligations is unsound. It appears that the Appellate Body's conclusion was based on the fact that, if not all, of the scientific studies referred to by the EC concluded that the use of the five hormones in question for growth promotion purposes was safe.⁸⁹ The EC prohibition was held to have violated the Article 5.1 requirement that an SPS measure be 'based on' risk assessment because it did not conform to the outcomes of the scientific studies cited.⁹⁰ Conformity requires that the contested measure reflected the findings of scientific risk assessments. On the basis of the Appellate Body's interpretation of 'based on' as meaning 'conforming to', it can be argued that the extent to which scientific evidence is upheld by an SPS measures is pivotal to its legitimacy under the WTO regime.

⁸⁵ Appellate Body Report at paragraph 200.

⁸⁶ Ibid.

⁸⁷ *Ibid.* at paragraph 196.

⁸⁸ Wirth, D. A. 'The Role of Science in the Uruguay Round & NAFTA Trade Disciplines' (1994) 27 Cornell International Law Journal 817, at page 857.

⁸⁹ US Panel Report at paragraph 8.124; Canada Panel Report at paragraph 8.127; Appellate Body Report at paragraph 206.

⁹⁰ Appellate Body Report at paragraph 192.

Yet, this narrowly scientific approach is manifestly inconsistent with the way in which the Appellate Body subsequently extended the definition of 'risk' so as to encompass non-scientific factors. Accordingly, risk assessment under Article 5.1 should not be confined to an evaluation of the risk ascertainable in a science laboratory operating under strictly controlled conditions.⁹¹ Furthermore, the Appellate Body held that the Panel had erred in its finding that all risk was necessarily quantifiable, and that the term 'risk' could also be used to denote unquantifiable threats, definable only by qualitative means.⁹² The interpretation of risk as qualitative measurement is perhaps the only evidence in the entire judgment that the Appellate Body was prepared to accept subjective risk *perception* as an appropriate factor in the setting of trade barriers. Indeed, the judgment can be described as displaying a polarization between perceived and objective measurements of risk. Whilst the Appellate Body recognised that risk assessment could take into consideration nonscientific, unquantifiable factors,⁹³ it was also of the opinion that the EC measure ought to reflect the outcome of the scientific risk assessment that the use of the hormones at issue was safe. Whereas the Appellate Body seemingly permitted a liberal approach to risk assessment, it was simultaneously intolerant of the endorsement of anything other than mainstream scientific evidence.

This leads to the third inconsistency of the ruling. Despite acknowledging the divergent opinions presented by different scientists as an acceptable basis for risk assessment,⁹⁴ and given that the Article 5.1 stipulation that an SPS measure must be 'based on' risk assessment was interpreted as requiring the measure to reflect scientific findings, it is surprising that the Appellate Body rejected evidence submitted by one scientist as having a rational relationship with the contested measure. Dr Lucier, an expert advising the EC and the Dispute Resolution Panel, claimed that the consumption of meat treated with exogenous oestrogens posed a threat to human health, stating that:-

"[f]or every million women alive in the United States, Canada, Europe today, about a 110,000 of those women will get breast cancer. This is

⁹¹ *Ibid.* at paragraph 187.

⁹² *Ibid.* at paragraph 186.

⁹³ Macmillan, F. (2001) at page 150, section 6.15.

⁹⁴ Appellate Body Report at paragraph 194.

obviously a tremendous public health issue. Of those 110,000 women who get breast cancer, maybe several thousand of them are related to the total intake of exogenous oestrogens from every source, including eggs, meat, phyto-oestrogens, fungal oestrogens, the whole body burden of exogenous oestrogens. And by my estimates one of those 110,000 would come from eating meat containing oestrogens as a growth promoter, if used as prescribed."⁹⁵

Mindful of the fact that the other scientific studies cited by the EC were criticised for failing to address the specific risk posed by the five hormones in dispute, it is at least arguable that Dr Lucier's assessment of the potential risks was sufficiently specific for the purposes of paragraph 4. Given that oestradiol- 17β is an exogenous oestrogenic derivative, it is unclear precisely why the Appellate Body concluded that the evidence lacked sufficient detail.

The Appellate Body avoided ascertaining whether Dr Lucier's submission satisfied the specificity requirement of paragraph 4. Instead, it argued that the evidence provided by Dr Lucier produced results "not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities".⁹⁶ It appears that, on concluding that the results of Dr Lucier's study were "not reasonably sufficient", the Appellate Body was making reference to the *magnitude* of the risk, and not the *specificity* of the study.

The Appellate Body's dismissal of Dr Lucier's submission conflicts with the way in which it had previously interpreted the notion of risk assessment as incorporating the opinion of scientists taking divergent views, and not necessarily embodying the view of the majority of the scientific community.⁹⁷ The acknowledgment by the Appellate Body that divergent views were welcomed⁹⁸ suggests that the EC position was incontestable. Arguably, Dr Lucier's evidence reasonably supported⁹⁹ the EC import

⁹⁵ US and Canada Panel Reports, Annex, paragraph 819; Appellate Body Report, at paragraph 198, note 181.

⁹⁶ Appellate Body Report, at paragraph 198.

⁹⁷ *Ibid.* at paragraph 194.

⁹⁸ *Ibid*.

⁹⁹ Ibid. at paragraph 193.

ban, giving rise to a 'rational relationship' between the risk assessment and contested measure.¹⁰⁰

On the basis of these inconsistencies, it can be concluded that there was little to warrant the narrow approach eventually adopted by the Appellate Body. It is conceivable that, had it upheld its liberal interpretation of the process of risk assessment, and had it given due attention to the observable specificity of Dr Lucier's evidence, the Appellate Body would have found that there existed a sufficient relationship between the EC measure and its underlying risk assessment. Instead, the WTO resorted to a strictly scientific approach, which is reflected in its attitude towards the definition of risk. Notwithstanding its ostensible attempt to extend the boundaries of its definition to include qualitatively measurable risk, the Appellate Body only examined the risk in respect of its physical implications, and not in the context of the consumer perception of that risk.

3.3 WTO and the precautionary principle

On reading the Reports of both the Panel and the Appellate Body, it becomes apparent that a clear-cut distinction was made between the precautionary principle as it is embodied in Article 5.7, and the precautionary principle as a customary rule of international environmental law. The tension between Article 5.7 and the notion of precaution as a customary rule was undoubtedly a central theme of the rulings. This distinction is crucial in demonstrating that both the definition and application of the precautionary principle is inherently context-dependent. Instead of invoking Article 5.7, the EC claimed that its import ban was justified by the precautionary principle as a customary rule of international law – because the narrowly-scientific confines of Article 5.7 did not support the broader rationale underlying the contested Directive.

In determining the implementation of the precautionary principle, the EC took into account factors beyond the margins of Article 5.7. Indeed, in the light of the approach

¹⁰⁰ *Ibid.* at paragraph 189.

adopted by EC institutions in *Re Agricultural Hormones*,¹⁰¹ it is reasonable to suggest that the Community's reliance on the precautionary principle at the WTO hearing was reflective of its attempts to maintain consumer confidence in the safety of meat. This is a particularly credible argument in view of the fact that the majority of scientific studies presented by the EC concluded that the use of the hormones at issue posed a statistically *negligible* threat to human health. In accordance with the scientific constraints of Article 5.7, much of the evidence available to the EC at the time indicated that any human health risk associated with the use of anabolic agents was insignificant, and, on the basis this information, precautionary action was scientifically unjustifiable. Yet, the remit of the EC's interpretation of 'uncertainty' was far broader than its counterpart in Article 5.7. Whereas the application of precaution through Article 5.7 was based on the fact that, according to scientific consensus, it could be said with a degree of scientific certainty that the use of hormones posed no, or very little, risk, the EC adopted a more liberal notion of 'precaution', taking into account uncertainty stemming from extra-scientific sources. From this perspective, it can be said that the EC's stance mirrored the opinion of Advocate General Lenz in Re Agricultural Hormones that the invocation of the precautionary principle rested on the protection of public interests in general, which required an examination of factors outside the scope of scientific assessment, and not confined to the protection of consumer health, which was solely a matter for scientific determination.

The disparity between Article 5.7 and the precautionary principle as a 'customary rule' can be seen as a product of differences not only in the operational significance attributed to scientific evidence, but also in the regimes from which they derive. Whilst Article 5.7 is a component of a trade liberalisation regime, the principle of precaution as relied upon by the EC developed from a scheme of environmental and human health protection. Thus, the concept of precaution pursuant to Article 5.7 and precaution as an element of customary international law are irreconcilable for as long as they continue to have different priorities. The natural conclusion to draw is that, despite talk of 'the' precautionary principle, its definition and interpretation ultimately depends on the context within which it is being applied.

¹⁰¹ [1988] 2 C.M.L.R. 543.

Although the Appellate Body did not explicitly admit that this was the case, its ruling can be interpreted as an implicit rejection of the argument that a separate precautionary principle created an obligation in customary international law. Not only does this reflect the lacking international consensus as to its definition and content, but it is also a sign of the Appellate Body's scepticism of the feasibility of forms of the precautionary principle developing from beyond the boundaries of the trade liberalisation regime. Interestingly, in a subsequent report published by the Council for Responsible Nutrition (CRN), it was observed that a precautionary principle model other than that espoused by Article 5.7 is "not needed and is potentially harmful, because it would be redundant and falsely imply that there is no precaution in risk management without it",¹⁰² going on to note that "a separate precautionary principle would be an open invitation to erect unjustified technical barriers to trade".¹⁰³ Reflecting the underlying attitude of the Appellate Body in WTO Beef Hormones, the CRN considered that the precautionary principle, as a customary rule of international law, provided an opportunity for arbitrary decision-making, interpreting it as merely a justificatory tool to frame otherwise unrelated decisions in terms of environmental protection.

This leads to an important conclusion. Whereas previous academic commentaries have tended to point to the significance of the *Beef Hormones* Dispute as existing in the willingness of the Appellate Body to acknowledge the concept of precaution in the framework of Article 5.7,¹⁰⁴ they overlook the more subtle reasoning that the ruling represents an implicit *rejection* of the usefulness of precautionary principle as an undefined and ambiguous rule of customary rule of international law.

 ¹⁰² Codex Alimentarius, Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, Consideration of the Elaboration of Standards, Guidelines or Other Principles for Foods Derived from Biotechnology (February 2000) Document CX/FBT 00/4, Part I, at page 27.
 ¹⁰³ Ibid.

¹⁰⁴ Macmillan, F. (2001) at pages 154-155.

3.4 Post-Beef Hormones

3.4.1 Japan – Measures Affecting Agricultural Products¹⁰⁵

The precautionary principle became the focus of attention for the WTO Dispute Settlement Body again in 1999 following a complaint made by the United States in respect of the requirement imposed by Japan to test and confirm the efficacy of the quarantine treatment for varieties of particular agricultural products ('the varietal testing requirement').¹⁰⁶

Japan had previously prohibited importation of eight agricultural products – apples, cherries, peaches (including nectarines), walnuts, apricots, pears, plums and quince – from the United States on the basis that they were potential hosts to a species of pest, the codling moth, presenting a potential risk to the yield of Japanese agriculture.¹⁰⁷ The import prohibition could only be lifted if the exporting country was able to demonstrate the exercise of an alternative quarantine procedure that achieved the required level of protection. The efficacy of the alternative quarantine procedure could be tested against two guidelines set out by the Japanese Ministry of Agriculture, Forestry and Fisheries. The first set out a number of testing requirements which had to be satisfied before the import prohibition could be lifted.¹⁰⁸ The second outlined the procedure of approving varieties of a particular product, called 'the varietal testing requirement'.

The United States claimed that the varietal testing requirement was inconsistent with the obligations under the SPS Agreement. The Panel Report, which was delivered on 27 October 1998, found that Japan had acted inconsistently with Articles 2.2, 5.6 and 7 of the SPS Agreement.¹⁰⁹ Accordingly, the process of varietal testing in respect of the import of apples, cherries, nectarines and walnuts violated Article 2.2 which

¹⁰⁵ Report of the Appellate Body AB-1998-9, WT/DS76/AB/R, 22 February 1999.

¹⁰⁶ Japan – Measures Affecting Agricultural Products, AB—1998-9, WT/DS76/AB/R, at paragraph 1.

¹⁰⁷ Prohibition made on the basis of the Plant Protection Law, Law No. 151, enacted on 4 May 1950; and the Plant Protection Law Enforcement Regulation, Ordinance No. 73 of the Ministry of Agriculture, Forestry and Fisheries, enacted on 30 June 1950.

¹⁰⁸ the Experimental Guideline for Lifting Import Ban – Fumigation, see Japan – Measures Affecting Agricultural Products, at paragraph 2.

¹⁰⁹ Japan – Measures Affecting Agricultural Products, at paragraph 3.

imposed an obligation on Members not to maintain SPS measures without scientific evidence of a risk to the environment.¹¹⁰ The varietal testing requirement was also incompatible with Article 5.6 which compelled Members to ensure that measures were not more trade-restrictive than required to achieve Japan's appropriate level of phytosanitary protection, taking into account its technical and economic feasibility. And, given that Japan did not publish the varietal testing requirement in respect of any of the agricultural products in question, the requirement was inconsistent with paragraph 1 of Annex B, and as a result, breached Article 7.

Pursuant to Article 16, paragraph 4, of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Japan appealed against the legal issues arising in Panel Report, filing its submission on 4 December 1998.¹¹¹ In relation to Article 2.2, Japan claimed that the Panel Report failed to give due regard to the precautionary principle¹¹² – submitting that the varietal testing requirement needed to be understood in the context of a precautionary ethos, particularly given that the precautionary principle was reflected in both the Codex Alimentarius¹¹³ and the UN Food and Agriculture Organisation (FAO) Guidelines for Pest Risk Analysis.¹¹⁴ Japan claimed that the Panel had erred in its decision that there was no 'actual causal link' between the contested measure and scientific evidence, and in doing so, had denied the operation of the precautionary principle.¹¹⁵ It argued that the varietal testing requirement was 'an information requirement'¹¹⁶ – which was justifiable even where there is only "some available information suggesting some risk."¹¹⁷

Conversely, the US argued that there was no "objective and rational relationship"¹¹⁸ between the varietal testing requirement and the scientific evidence required by Article 2.2 SPS, and that the precautionary principle should not be used as a ground for justifying an SPS measure which was otherwise inconsistent with SPS

¹¹⁵ Japan – Measures Affecting Agricultural Products, at paragraph 9.

¹¹⁰ Article 2.2 – applies except as provided for in paragraph 7 of Article 5.

¹¹¹ WT/DS76/5.

¹¹² Japan – Measures Affecting Agricultural Products, at paragraph 10.

¹¹³ Codex Alimentarius, General Principles for the Use of Food Additives (1995) Document CX/GP 00/3-Add 6, Vol. A1.

¹¹⁴ International Standards for Phytosanitary Measures Part I – Import Regulations, Guidelines for Pest Risk Analysis, Food and Agriculture Organisation Secretariat 1996.

¹¹⁶ *Ibid.* at paragraph 8

¹¹⁷ Ibid.

¹¹⁸ *Ibid.* at paragraph 20

obligations.¹¹⁹ Furthermore, the US asserted that there was only a *theoretical* risk and that Japan was not permitted to justify its measure without ascertainable scientific evidence of potential harm.¹²⁰

The Appellate Body upheld the Panel's finding that there must be a rational and objective relationship between the SPS measure and scientific evidence of a potential risk.¹²¹ Moreover, it noted that if the 'rational and objective relationship' requirement were to be discarded, Article 5.7 would be rendered impotent, given that its operation is limited to cases "where relevant scientific evidence is insufficient."¹²² With regard to this interpretation, the Appellate Body concluded that the varietal testing measure had been maintained *without* sufficient scientific evidence.¹²³ Evidence that there *may* have been varietal differences which were likely to affect the efficacy of quarantine treatment was merely speculative,¹²⁴ and the threat of the entry of the codling moth into agricultural systems was seen as only 'a possibility'.¹²⁵

Reflecting the findings in the WTO *Beef Hormones* Case, the Appellate Body held that the precautionary principle was already upheld by Articles 3.3 and 5.7 of the SPS Agreement.¹²⁶ In particular, regard was given to Article 5.7, which, as a manifestation of the concept of precaution, stipulates that a four-stage test must be satisfied before invocation.¹²⁷ First, a Member may provisionally adopt a precautionary SPS measure is imposed in respect of a situation where 'relevant scientific information is insufficient'.¹²⁸ Second, a measure must be adopted on the basis of 'available pertinent information'.¹²⁹ Third, the adoption of a provisional measure is prohibited unless the Member seeks to obtain additional information

¹¹⁹ *Ibid.* at paragraph 21

¹²⁰ *Ibid.* at paragraph 22

¹²¹ *Ibid.* at 84; see also Panel Report paragraphs 8.29 and 8.42.

¹²² note that the Appellate Body found that although the contested measure was considered to be a provisional measure according to the first sentence of Article 5.7 SPS, Japan had not fulfilled the requirements contained in the second sentence of Article 5.7 SPS Agreement – see Japan – Measures Affecting Agricultural Products, at paragraph 143(b).

¹²³ Appellate Body Report Japan – Measures Affecting Agricultural Products, at paragraph 85.

¹²⁴*Ibid.* at paragraph 21.

¹²⁵ *Ibid.* at paragraph 42.

¹²⁶ *Ibid.* at paragraph 81.

¹²⁷ *Ibid.* at paragraph 89

¹²⁸ Article 5.7 SPS, first sentence.

¹²⁹ Ibid.

necessary for a more objective assessment of risk.¹³⁰ Finally, subsequent to adoption, the Member is obliged to review the measure accordingly within a reasonable period of time.¹³¹

Despite recognising the existence of the precautionary principle within the Article 5.7 framework, the Appellate Body reiterated that it had not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in other provisions of that Agreement.¹³² Reflecting the finding in the *Beef Hormones Dispute*, an implicit aspect of the ruling was that there was no overarching duty arising independently of obligations under the SPS Agreement to apply the precautionary principle. In curtailing the application of the precautionary principle as a broader legal mandate that would threaten to supersede existing SPS provisions.¹³³ Although it remained silent as to the international status of the principle, the Court's explicit restriction of precaution to Article 5.7 can be construed as an outright rejection of the precautionary principle derived from alternative regimes.

Even in the aftermath of the WTO *Beef Hormones* Dispute, the Appellate Body continued to be ill at ease with the concept of precaution as a general customary rule of international law, presumably as a result of a deep-seated concern not only for its lack of precise definition and application, but also for its potentially devastating implications on the aims and objectives of the trade harmonisation regime. Had it felt that the precautionary principle had a sufficiently normative character, then it is conceivable that the Appellate Body would have been drawn into some discussion of its international legal status as a customary rule. However, mindful of the notorious ambiguity surrounding its definition and the implications of its application, it is likely that the Appellate Body considered it futile to make a universal declaration on a principle so lacking in universal content.¹³⁴

¹³⁰ Article 5.7 SPS, second sentence.

¹³¹ Ibid.

¹³² Japan – Measures Affecting Agricultural Products, at paragraphs 81 and 124.

¹³³ *Ibid.* at paragraph 21

¹³⁴ See Birnie, P. W. and Boyle, A. E. (eds) (1992) at page 98.

Three principal observations can be made in relation to the approach taken by the WTO Panel and Appellate Body in both the Beef Hormones and the Japanese Agricultural Measures rulings. First, both rulings suggest that the Panel and Appellate Body were hostile to the level of generality at which the precautionary principle was pitched by the EC and Japan, respectively. Second, and more specifically, the rulings indicate that the reconciliation of precaution and trade harmonisation is only possible within the narrowly-prescribed confines of Article 5.7. Third, the approach taken by both the Panel and Appellate Body was unquestionably science-based, implying that the notion of precaution was subordinate to the more pressing need to base measures on a thorough scientific assessment. The overriding theory, however, is that a definite disparity exists in the scope of application between precautionary principle in relation to specific provisional measures under the SPS Agreement and the precautionary principle as a general norm of international law. Defining the scope of its operation depends on whether it is being interpreted either narrowly within the margins of Article 5.7, or in a broader manner as a customary rule. Hence, both the meaning and application of the precautionary principle vary according to the context within which they exist. It can thus be described as an intrinsically relative instrument.

The apprehensiveness demonstrated at the WTO was replicated by the International Court of Justice in the Southern Bluefin Tuna Cases,¹³⁵ which, although endorsing precautionary approach, remained guarded about the possibility of the precautionary principle imposing legal obligation as a result of its acceptance at a general customary level. Arguably, however, the opinions expressed by Judge Treves, Judge Laing and Judge *Ad Hoc* Shearer go beyond the WTO Dispute Resolution Bodies in that they are somewhat more amenable to the possibility of the principle having attained customary status.

¹³⁵ International Tribunal for the Law of the Seas Order in the Southern Bluefin Tuna Cases (Requests for Provisional Measures) (*New Zealand v Japan*; *Australia v Japan*), 27 August 1999.

• <u>3.4.2 The Southern Bluefin Tuna Cases¹³⁶</u>

A joint claim was brought by Australia and New Zealand against Japan's experimental fishing programme. All three States were associates of the Commission on the Conservation of Bluefin Tuna.¹³⁷ Japanese catches of Southern Bluefin Tuna exceeded the allocated quota under Commission framework.¹³⁸

Australia and New Zealand instigated an arbitration procedure pursuant to Annex VII of United Nations Convention on the Law of the Sea, and filed a request for provisional measures to prevent the continuation of Japanese fishing programme with the International Tribunal for the Law of the Sea. In their Statements of Claim, Australia and New Zealand alleged that Japan was in breach of its obligations under Articles 64 and 116-119 of the UN Convention on the Law of the Sea by "failing in its obligations under UNCLOS in respect of the conservation and management of SBT [Southern Bluefin Tuna], having regard to the requirements of the precautionary principle",¹³⁹ and requested that Japan "immediately cease unilateral experimental fishing for SBT [and] that parties act consistently with the precautionary principle in fishing for SBT pending a final settlement of the dispute."¹⁴⁰

Japan claimed that there was no evidence to suggest that the experimental fishing programme posed a risk to the Southern Bluefin Tuna stock, and argued that the programme was in fact a necessary course of action in order to assess the potential of the stock to recover in numbers.¹⁴¹ Furthermore, it claimed that "it was doubtful that the precautionary principle had attained the status of a rule of customary international law."¹⁴²

The Tribunal Order prescribed provisional measures to prevent serious harm to the marine environment,¹⁴³ displaying definite precautionary traits. It expounded a

¹³⁶ Ibid.

¹³⁷ Commission established under the 1993 Convention for the Conservation of Southern Bluefin Tuna

¹³⁸ Southern Bluefin Tuna Cases at paragraph 71.

¹³⁹ Statements of Claim of Australia and New Zealand, 15 July 1999, paragraph 69(1)(e).

¹⁴⁰ Southern Bluefin Tuna Cases at paragraphs 31 and 32.

¹⁴¹ *Ibid.* at paragraphs 33, 42, 47 and 73.

¹⁴² Arbitral Award on Jurisdiction and Admissibility in the Southern Bluefin Tuna Case, 4 August 2000 at paragraph 34.

¹⁴³ Southern Bluefin Tuna Cases at paragraphs 40-67.

classic three-stage precautionary model recognising: (i) that the severely depleted stock was evidence of the Japanese fishing practice posed a risk to Southern Bluefin Tuna; (ii) that the conflicting scientific evidence presented could be construed as scientific uncertainty; and (iii) and that, in the face of scientific uncertainty, it was necessary to act with prudence and caution.¹⁴⁴ Exhibiting a greater willingness than previously done so by the WTO Dispute Settlement Body to endorse the notion of precaution, the Tribunal accepted the notion of precaution as a pivotal component of international environmental protection. In particular, Judge Treves described a precautionary approach as being a 'necessary' course of action, particularly given the urgency of the situation,¹⁴⁵ and added that the reluctance of the Tribunal to take a position as to whether the precautionary approach was a binding principle of customary law was understandable.146 Yet, notwithstanding the Tribunal's discernible commitment to endorsement of a precautionary response to potential hazards, it was simultaneously ambivalent as to its legal status in international environmental protection. Judge Laing, for example, concluded that, although it was evident that the Tribunal had adopted a precautionary approach,¹⁴⁷ it was not possible. on the basis of the arguments presented, to determine whether the precautionary principle was a customary norm of international law.¹⁴⁸ In his opinion, he explained that:-

"[i]t might be noted that treaties and formal instruments use different language of obligation; the notion is stated variously (as a principle, approach, concept, measure, action); no authoritative judicial decision unequivocally supports the notion; doctrine is indecisive; and domestic juridical materials uncertain or evolving."¹⁴⁹

Likewise, Judge Ad Hoc Shearer asserted that is was unnecessary to enter into a debate in respect of the legal status of the precautionary principle, and that the

Ibid. at paragraphs 77 and 80, emphasis added; See also Fabra, A. 'The LOSC and the Implementation of the Precautionary Principle' (1999) 10 YB of Int'l Env L 15-24, at page 16.
 ¹⁴⁵ Separate Opinion of Judge Treves, paragraph 8.

¹⁴⁶ *Ibid.* at paragraph 9.

¹⁴⁷ Separate Opinion of Judge Laing, paragraphs 21,12 and 19.

¹⁴⁸ *Ibid.* at paragraph 16.

¹⁴⁹ *Ibid.* see footnote 5.
measures ordered by the Tribunal were "rightly based upon considerations deriving from a precautionary approach."¹⁵⁰

Despite the fact that Treves, Laing and Ad Hoc Shearer were of the opinion that it was neither possible nor desirable to make a ruling on the international legal status of the precautionary principle, Trouwborst nevertheless considered that, from a precautionary point of view, the Southern Bluefin Tuna case is "the most meaningful one so far".¹⁵¹ Yet, notwithstanding the conviction with which the judges cited the concept of precaution, the principle's legal implications remained elusive. According to Freestone, this explicit acceptance of the precautionary principle at international level is a sign that it as attained the status of a general rule of law.¹⁵² Similarly, Hey interprets the frequency with which precaution has been cited in international practice as evidence that it has crystallised into a binding customary rule.¹⁵³ Cameron insists that the impact of the precautionary principle extends beyond policy guidance, having legal effect as a general norm of international law.¹⁵⁴ Likewise, Sands claims that there is sufficient evidence of state practice to assume that the principle reflects a broadly accepted basis for international environmental protection, adding that its status as a customary rule is secured even though its content and application being may be open to interpretation.¹⁵⁵

However, academic commentaries claiming that the precautionary principle has evolved into a general and binding principle are mistaken in basing this assumption solely on the frequency of its invocation. Whilst the regularity of its occurrence is indicative of its notoriety, it does not necessarily point to its acceptance as a universal principle of international law. The problem is one of striking a balance between generality and specificity. By virtue of their nature, customary rules of international law are characteristically general in nature so as to achieve widespread application. The flipside is that excessive generality undermines the precautionary principle's

¹⁵⁰ Separate Opinion of Judge Ad Hoc Shearer.

¹⁵¹ Trouwborst, A. (2002) at page 173.

¹⁵² Freestone, D. (1991) at pages 36-7.

¹⁵³ Hey, E. 'The Precautionary Principle in Environmental Policy and Law: Institutionalizing Caution' (1992) 4 Georgetown International Environmental Law Review 303, at page 303.

¹⁵⁴ Cameron, J. (1994) at pages 266 and 279.

¹⁵⁵ Sands, P. 'The Greening of International Law: Emerging Principles and Rules' (1994) 1 Indiana Journal of Global Legal Studies, partly reprinted in D'Amato, A. and Engel, K. (eds) International Environmental Law Anthology (Cincinnati; Ohio; 1996) 21-22, and 28-29, at page 22.

normative disposition and thwarts any attempt to identify and articulate its core elements. Thus, a degree of specificity is required in order to determine its definition and application.

It is commonly accepted that a principle develops into a customary rule if it displays two elements.¹⁵⁶ First, it must be a given practice of states. Second, it must be accepted as being mandatory.¹⁵⁷ In its Report of the Sixty-Ninth Conference held in London, 2000, the International Law Association explained that general rules are created and sustained by the "constant and uniform practice of States and other subjects of international law",¹⁵⁸ and give rise to "a legitimate expectation of similar conduct in the future."¹⁵⁹ Logically, in order to satisfy these conditions, the precautionary principle must be practically viable and its operation sufficiently clear. Imprecision, to the extent that its core elements are largely unrecognisable, precludes uniformity of application in the sense that the huge variety of interpretations given to the precautionary principle conflict with efforts to generalise.¹⁶⁰ As Brown Weiss notes, "there is no agreement on the content of the principle, or even as to whether an actual principle has emerged or only an approach to address a problem.¹⁶¹ It is for this reason that, regardless of the frequency of its recognition, the legal bearing of the precautionary principle is prevented from extending to a customary law -aconclusion motivated by its lack of definitive interpretation - reflected by the fact that, at present, a state's failure to uphold the precautionary principle is not deemed to be an internationally wrongful act triggering state responsibility.¹⁶² Furthermore, as a result of its disputed application and scope in the international sphere, it becomes

¹⁵⁶ See, for example, Hohmann, H. Precautionary Legal Duties and Principles of Modern International Environmental Law (Dordrecht; 1994) at 172-173, identifying characteristics that mark the evolution of a customary rule. ¹⁵⁷ International Law Association 'Final Report of the Committee on Formation of Customary

⁽General) International Law & Statement of Principles Applicable to the Formation of General Customary International Law', in International Law Association Report of the Sixty-Ninth Conference, held in London 25-29th July 2000 (London; 2000) 712-790, at page 718; see also Brownlie, I. Principles of Public International Law (Oxford University Press; Oxford; 1998) at pages 4-9. ¹⁵⁸ paragraph 1(i) International Law Association (2000) at page 719.
 ¹⁵⁹ Ibid.

¹⁶⁰ Bosselmann, K. 'Power, Plants and power Plants: New Zealand's Implementation of the Climate Change Convention' (1995) 12 European Public Law Journal 423-439, at pages 431-432.

¹⁶¹ Brown Weiss, E. 'International Environmental Law: Contemporary Issues and the Emergence of a New World Order' (1993) 81 Georgetown Law Journal 690, as cited in Jurgielewicz, L.M. Global Environmental Change and International Law (Lanham; 1996) page 90, footnote 318.

¹⁶² Tinker, C. 'Responsibility for Biological Diversity Conservation Under International Law' (1995) 28 Vanderbilt Journal of Transnational Law 777-821 at page 796.

impossible to attach any meaningful explanation without reference to context. The precautionary principle, by virtue of its elusive character, is inherently dependent on its operational framework, and for that reason, subjectivity predominates its utilisation. Indeed, the judicial reluctance to furnish the precautionary principle with any functional substance is indicative of the reality that stand-alone definitions are void.

The WTO Panel is expected to deliver its judgment in relation to another trans-Atlantic dispute by the end of January 2006.¹⁶³ In 2003, the US, Canada, and Argentina challenged the EC over its *de facto moratorium* on the approval of genetically modified (GM) crops.¹⁶⁴ A number of other nations have also registered their interest as third parties affected by the outcome.¹⁶⁵ In a formal request for WTO Panel adjudication, the complaining Member States claimed that three measures were inconsistent with specific provisions of the SPS Agreement, GATT 1994, the Agreement on Agriculture, and the Agreement on Technical Barriers to Trade.¹⁶⁶

- 1. the EC moratorium on the approval of products of agricultural biotechnology which suspended consideration of applications for, or granting or, approval of biotech products under the EC approval system;
- 2. the blockage under EC existing legislation of all applications for placing further biotech products on the market; and
- 3. the maintenance by EC Member States of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC.

¹⁶³ In relation to the European Communities Measure Affecting the Approval and Marketing of Biotech Products. See complaints lodged before the WTO Dispute Resolution Panel by the United States (DS 291/17), Canada 292/17) and Argentina (293/17). Despite early indications that a preliminary ruling may be passed down before the end of 2005, the Panel has delayed its ruling until January 2006.

¹⁶⁴ European Communities – Measures Affecting the Approval and Marketing of Biotech Products WT/DS 291, 292 and 293.

¹⁶⁵ Australia, Brazil, Chile, China, Chinese Taipei, Columbia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Thailand, and Uruguay.

¹⁶⁶ Request for the Establishment of a Panel by the United States, WT/DS291/23 (8 August 2003).

Without going into the finer details of the arguments presented by the parties, it is worth drawing attention to the *amicus curiae* brief submitted on 30 April 2004^{167} – the value of which lies in its explicit recognition that the strict scientific interpretation of the SPS Agreement is inconsistent with the argument that risks "are defined, and hence can be meaningfully interpreted and evaluated, only within particular political and cultural contexts."¹⁶⁸ The brief supports the claim that risk assessment is neither a single methodology, nor a 'science'.¹⁶⁹ Instead, and contrary to the US position, the brief asserts that the notions of 'risk' and 'risk assessment' must be reconceptualised¹⁷⁰ in order to account for the fact that they both vary with context.¹⁷¹ It observes that, although risk assessment has often been presented as an objective, science-based, value-free analytical exercise,¹⁷² both science and policy would be better served by acknowledging the scientific limits of risk assessment.¹⁷³ This is an interesting position, particularly in the light of the overwhelming consensus within regulatory circles is that science is a universally-valid expert analytical process. As this thesis shows, however, scientific knowledge is neither uniform nor complete especially so in relation to environmental protection and food safety issues, given their 'special cultural status in human society'.¹⁷⁴

The following chapter focuses on the relationship between the concept of 'risk' and the precautionary principle in EC regulation. It points to the tendency within EC institutions to regard precaution as a component of risk assessment, and in addition to

¹⁶⁷ The groups can be broadly divided:- the first group comprises of a number of expert academics (Professors Brian Wynne, Robin Grove-White, Shelia Jasanoff, Lawrence Busch, and Mr David Winickoff); the second group is made up of GeneWatch UK, Foundation for International Environmental Law and Development (FIELD, UK), Five Year Freeze (UK), Royal Society for the Protection of Birds (RSPB, UK), The Center for Food Safety (USA), Council of Canadians, Polaris Institute (Canada), Grupo de Relexion Rural Argentina, Center for Human Rights and the Environment (CEDHA, Argentina), Gene Campaign (India), Forum for Biotechnology and Food Security (India), Fondacion Sociedades Sustentables (Chile), and Greenpeace International.

¹⁶⁸ Busch, L. et al, Amicus Curiae Brief Submitted to the Dispute Settlement Panel of the World Trade Organisation in the Case of 'EC: Measures Affecting the Approval and Marketing of Biotech Products', 30 April 2004, at page 15. Full text of amicus available at http://www.lancs.ac.uk/fss/ieppp/WTOamicus, accessed August 2005.

¹⁶⁹ *Ibid.* at page 5. ¹⁷⁰ *Ibid.*

¹⁷¹ *Ibid.* at page 6.

¹⁷² See, for example, World Health Organisation, Application of Risk Analysis to Food Standards Issues, Report of the Joint FAO/WHO Expert Consultation, Geneva, March1 1995, at page 6.

¹⁷³ Busch, L. et al (2004) at page 12. See also Silbergeld, E. K. 'Risk Assessment and Risk Management: An Uneasy Divorce', in Mayo, D. G. and Hollander, R. D. (eds) Acceptable Evidence: Science and Values in Risk Management, 99-114, at page 99.

¹⁷⁴ Ibid. at page 18. See also, Echols, M. A. Food Safety and the WTO: The Interplay of Culture, Science, and Technology (Kluwer Law International; The Hague; 2001) at pages 148-155.

this association, to view risk in isolation. This connection between the operation of the precautionary principle and scientific risk analysis finds itself at the heart of hazard regulation in the EC, and this is particularly evident in relation to the structure of the European Food Safety Authority (EFSA). There is some evidence, however, that the recent judicial treatment of precaution is departing from its traditional reliance on quantitative definitions of risk to an evaluation based on qualitative information. Chapter Four introduces the interface between precaution and science-based risk assessment, before turning to examine trends in case law that suggest a liberalisation of the meaning of 'risk' so as to include perceptions of impending hazards that are shaped by normative priorities, culture, and experience. Chapter Five continues with this theme, presenting the precautionary principle in UK law and policy. It illustrates that, because it is neither feasible (nor desirable) to demarcate risk assessment as a purely technical phase, definitions of 'risk', and as a result the application of precaution, vary according to context.

Chapter Four

The precautionary principle in EC environmental protection

4.0 Introduction

The notion of precaution has long featured in the regulatory philosophy of the EC. Precautionary measures were being taken for some time before the 'precautionary principle' was explicitly incorporated into the Treaty of Rome by the Maastricht Treaty in 1992.¹ Its historical relationship with the EC derives from its early development in the environmental protection regimes of Member States. The first legal use of the notion of precaution can be traced to the Swedish Environmental Protection Act of 1969, which reversed the burden of proof in respect of environmentally hazardous activities,² and required industry to demonstrate safety of products to regulators before their use.³ In West Germany, environmental precaution emerged as a consequence of the Social Democrat election victory in 1969 which established a government eager to enforce its environmental credentials.⁴ The subsequent 1974 Clean Air Act employed the term 'vorsorge', which has since been deemed by many academics to mark the emergence of the precautionary principle in environmental protection. Following its initial stages of development in domestic law, precautionary thinking became the focus of supranational regulation. Following intense German lobbying during North Sea deliberations, the EC adopted the precautionary principle as a standard environmental policy.⁵

Notably, early anticipatory provisions tended to refer to a precautionary 'measure' rather than 'principle'.⁶ For example, a Council Decision concerning the release of

¹ For full text see (1992) 31 *ILM* 247.

² Miljoskyddslagen 29 May 1969 Stockholm, Swedish Government.

³ Löfstedt, R. 'The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis' (2004) 28(3) Journal of Risk and Uncertainty 237-260, at page 243.

⁴ Weidner, H. "Umweltpolitik: Auf altem Weg zu einer internationalen Spitzenstellung', in Suss, W. (ed) *Die Bundesrepublik in den achtziger Jahren. Innen Politik, Kultur, Aussenpolitik. (*Frankfurt; Opladen; 1991) as cited in Löfstedt, R. (2004) at page 244.

⁵ Löfstedt, R. (2004) at page 244. See also Commission of the European Communities, First Environmental Action Programme 1973-1976 OJ 1973 C112.

⁶ See for example, Directive 80/876 EEC on the approximation of the laws of Member States relating to straight ammonium nitrate fertilizers of high nitrogen content, OJ L250 23/09/1980, page 0007-0011, Article 9(3).

chlorofluorocarbons into the environment, delivered in March 1980, stated that "a significant reduction should, *as a precautionary measure*, be achieved in the next few years in the use of chlorofluorocarbons giving rise to emissions".⁷ Similarly, Directive 80/1095,⁸ which was designed to ensure that the Community remained free from classical swine fever, provides that, in the event of swine fever spreading alarmingly in Community territory, Members States may "take *the precautionary measures they deem appropriate*, including the reintroduction of organized preventive vaccination."⁹ In 1982, a Communication from the Commission concerning the marketing and use of plant protection products considered that "a number of precautionary measures … should be taken"¹⁰ so as to prevent the materialization of any risks to human health or the environment posed by the use of trichlorophenoxyacetic acid as a herbicide. The distinction between a precautionary *measure* and the precautionary *principle*, however, is largely rhetorical, without practical implication.¹¹

As 'precautionary spotting' illustrates,¹² the principle is deeply embedded in EC environmental protection. Whilst some consider the referencing of examples of precaution as strengthening the case for its legitimacy,¹³ others regard that the citing of infinitely divergent definitions demonstrates the fact that the precautionary principle is 'mere mush'.¹⁴ For the purposes of illustrating the extent to which the

⁷ Council Decision 80/372 26 March 1980 concerning chlorofluorocarbons in the environment, OJ L090 03/04/1980 page 0045-0045, Preamble, emphasis added.

⁸ OJ L325 o1/12/1980 page 0001-0004.

⁹ Article 6(3) Directive 80/1095 EEC, emphasis added.

¹⁰ Commission of the European Communities, Communication from the Commission to the Council: Concerning the Marketing and Use of Plant Protection Products, COM(82)332 final, OJ C170 08/07/1982, page 0006, at paragraph III.3.

¹¹ See, for example, The International Union for the Conservation of Nature and Natural Resources, *Guidelines for Applying the Precautionary Principle to Biodiversity Conservation and Natural Resource Management*, October 2005, which treats the 'precautionary principle' and 'precautionary approaches' as the same concept. See also Haigh, N. 'The Introduction of the Precautionary Principle into the UK', in O'Riordan, T. and Cameron, J. (eds) *Interpreting the Precautionary Principle* (Earthscan Publications Ltd; London; 1994) at page 238.

¹² Fisher. E. 'Precaution, Precaution Everywhere: Developing a 'Common Understanding of the Precautionary Principle in the European Community' (2002) 9(1) Maastricht Journal of European and Comparagraphtive Law 7, at Section C.

¹³ Harding, R. and Fisher, E. (eds) Perspectives on the Precautionary Principle (Federation Press; Sydney; 1999) see Appendix .

¹⁴ Fisher, E. (2002) at page 14; see also Morris, J. 'Defining the Precautionary Principle', in Morris, J. (ed) *Rethinking Risk and the Precautionary Principle*, at page 1; McKinney, W. J. and Hammer Hill, H. 'Of Sustainability and Precaution: The Logical, Epistemological and Moral Problems of the Precautionary Principle and Their Implications for Sustainable Development' (2000) 5(1) *Ethics and Environment* 77.

principle infiltrates environmental protection, a degree of 'precaution spotting' is unavoidable. The following examples are lifted not only in an attempt to demonstrate the frequency with which the precautionary principle is referred to, but also in an effort to impart a sense of the significance bestowed upon it in this context. It is shown that the precautionary principle is looked upon as central tenet in the EC legal order.

4.1 The significance of the precautionary principle in the EC

Support for the precautionary principle is institution-wide. It is clear that the EC institutions advocate the precautionary principle as an integral part of its environmental strategies – most notably in the fields of climate change,¹⁵ ozone protection¹⁶ and food safety.¹⁷ The 1997 Commission Communication on Consumer Health and Food Safety,¹⁸ for example, pledges that "the Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists".¹⁹ The European Parliament, in its Resolution on the 1997 Green Paper on General Principles of Food Law,²⁰ stressed that "policy in this area must be founded on a scientifically-based risk analysis supplemented, where

¹⁵ See, for example, Council Resolution on a Community programme of policy and action in relation to the environment and sustainable development - A European Community programme of policy and action in relation to the environment and sustainable development, OJ C 138, 17 May 1993, pages 1-4.

¹⁶ See, for example, Article 1 of Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air; Article 13 of Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants.

¹⁷ See, for example:-

[•] Paragraph 6 of Commission Decision 2000/325 authorising Member States to take measures provisionally against the introduction into, and the spread within the Community of Pepino mosaic virus as regards tomato plants, intended for planting, other than seeds (notified under document number;

[•] Paragraph 110 of Commission Decision 1999/835 on the national provisions notified by the Kingdom of Denmark concerning the limitation to the placing on the market and use of creosote;

[•] Article 4 of Directive 1999/50/EC amending Directive 91/321/EEC on infant formulae and follow-on formulae; and

[•] Article 4 of Directive 1999/39/EC amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children.

¹⁸ COM(97)183 final.

¹⁹ *Ibid.* 30 April 1997, at page 20.

²⁰ European Community Parliament, Resolution on the Commission Green Paper on General Principles of Food Law in the EU COM(97)176 final, OJ C104/61 10 March 1998.

necessary, by appropriate risk management based on the precautionary principle"²¹ In 1999, the Council 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".²²

This commitment is evident throughout Community policy.²³ For example, EC Environmental Action Programmes (EAPs), which formulate strategic policy to reflect the fundamental elements of environmental thinking,²⁴ have long recognised a pre-emptive approach to environmental risk.²⁵ Although Gervais notes that EAPs have not always reflected the notion of anticipatory conduct, she observes that their

- Paragraphs 2(u) and 7 of Regulation 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;
- Paragraph 5 of Council Decision 2002/628 concerning the conclusion, on behalf of the EC, of the Cartagena Protocol on Biosafety;
- Paragraph 17 of Regulation 852/2004 on the hygiene of foodstuffs;
- Paragraph 14 of Directive 2004/37 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;
- Paragraph 22 of Regulation 1946/2003 on transboundary movement of genetically modified organisms;
- Paragraph 3 of Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;
- Paragraph 2(1) of Council Regulation 2371/2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy;
- Chapter II(b) of the European Parliament Recommendation concerning the implementation of Integrated Coastal Zone Management in Europe;
- Paragraph 1 of Directive 2001/42 on the assessment of the effects of certain plans and programmes on the environment; and
- Article 4(1) of Directive 2001/18 on the deliberate release into the environment of genetically modified organisms.

²¹ *Ibid.* at paragraph 22.

²² Resolution 1999/C 206/01, at paragraph II(3). Other examples of the application of precaution in EC policy include:-

²³ Resolution on Endocrine-Disrupting Chemicals, OJ C341 09/11/1998, page 0037; Resolution on the Transatlantic Economic Partnership and EU/US Trade Disputes, Especially Hormones, Bananas and Hushkits, OJ C279 01/10/1999, page 0215; CEC White Paper on Food Safety COM (1999) 719 final; Common Position No.51/2000 of November 2000 adopted by the Council in relation to the adopting of a Directive on national emission ceilings for certain atmospheric pollutants, OJ C375 28/12/2000, pages 0001-0011; Commision of the European Communities, Application of the Precautionary Principle and Multi-annual Arrangements for Setting TACs, COM(2000)803 final; European Governance – A White Paper COM(2001) 428 final, OJ C287 12/10/2001; Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee: Strategy for Dioxins, Furans and Polychlorinated Biphenyls COM(2001)593 final, OJ C322 17/11/2001 pages 0002-0018.

 ²⁴ Hey, C. and Taschner, K. (eds) 'A Critical Evaluation of Available European Legislation on Industry and the Environment' (Dec 1998) *European Environmental Bureau Industry Handbook*, at section 2.
 ²⁵ See Commission of the European Communities, First Environmental Action Programme 1973-1976 OJ 1973 C112.

emphasis has gradually shifted from pollution control to pollution *prevention* and *precaution*.²⁶ Whereas the First Action Programme in 1972 focused on a remedial approach to waste disposal, the Sixth Action Programme²⁷ of 2001 asserted that "[w]here there is uncertainty about the risks but the effects or impacts are suspected to be potentially serious, a precautionary approach will be adopted",²⁸ before concluding that the precautionary principle "underpin[s] much of our current environmental legislation."²⁹

4.2 Article 174(2)

Explicit reference to the precautionary principle is made in Article 174 of the EC Treaty. Paragraph 2 of that Article states that EC environmental policy :-

"shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. *It shall be based on the precautionary principle* and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."³⁰

There is no doubt that the precautionary principle is imperative in the EC – and this is particularly evident when Article 174 is read in the light of Article 6, which provides that "environmental protection requirements must be integrated into the definition and implementation of *all other Community policy and activities*, in particular with a view to promoting sustainable development".³¹

Despite the centrality of precaution in the EC legal order, the Treaty avoids defining it, which might suggest that there is some tacit understanding of its meaning and

 ²⁶ Gervais, C. An Overview of European Waste and Resource Management Policy, Sustainable Economy Programme (Forum for the Future; London; May 2002) at section 3.1.
 ²⁷ Commission of the European Communities, Sixth Environmental Action Programme 2001-2010, OJ

²⁷ Commission of the European Communities, Sixth Environmental Action Programme 2001-2010, OJ 2002 L242.

²⁸ *Ibid.* at page 40.

 $^{^{29}}$ *Ibid.* at page 65.

 $^{^{30}}$ emphasis added.

³¹ emphasis added.

application. This is not the case. Academic inquiry has, for the large part, proceeded on the assumption that a fixed 'bright line' definition can be accomplished.³² However, as Stone rightly points out, it is impossible to define 'the' precautionary principle because there is no one version of the principle "elastic enough to wrap around all alternative institutional needs".³³ Underlying Stone's argument is the notion that the precautionary principle is too fluid a concept to be fixed by a single definition. Its intrinsic relativity is inconsistent with the drive to give it cast-iron meaning. The silence of Article 174(2), therefore, provides evidence that a universal definition is difficult, if not impossible, to achieve.

This fluidity was exemplified by the WTO Beef Hormones Dispute, in which the scope and definition of the precautionary principle was discernibly dependent on the context in which it operated. In that case, the term 'precautionary principle' was used in two very different senses. On the one hand, the WTO Panel and Appellate Body claimed that the precautionary principle was upheld by Article 5.7 SPS Agreement, which had a narrow focus on scientific interpretations of risk. On the other, the EC submitted that it was entitled to rely on the precautionary principle as a general rule of customary international law, whose application was relied on a broader understanding of risk and its social dimensions.

It is unsurprising that, in the aftermath of the *Beef Hormones* Dispute, the EC set about clarifying its position on the precautionary principle. The WTO ruling clearly gave the EC the impetus to establish a common interpretation of precaution and respond to the criticism that the EC's interpretation was impractical. The need for an official stance became more obvious still when concerns as to its meaning were raised by the Economic and Social Committee. The Committee noted that:-

"there are as yet few legal bases for the precautionary principle and that case law is still in its infancy. Explicit and implicit allusion to his principle does not provide a solid base, and the Economic and Social

³² see Fisher, E. (2002) at page 15; Sandin, P. et al 'Five Charges Against the Precautionary Principle' (2002) 5(4) Journal of Risk Research 287-299 at page 289; Gray, J. S. and Bewers, M. 'Towards a Scientific Definition of the Precautionary Principle' (1996) Marine Pollution Bulletin 32, 768-771, at page 768. ³³ Stone, C. D 'Is There a Precautionary Principle?' (2001) 31(7) *Environmental Law Reporter* 10790.

Committee would ask the Commission to submit a concrete, viable case soon."³⁴

In October 1999, a Commission official speaking at an inter-service working session in Brussels in October 1999 acknowledged the pressure on the EC to adopt a united front, admitting that "[w]e should consolidate the precautionary principle on human health and internal affairs".³⁵ Reacting to concerns over its definitional deficit, the Commission produced a Communication on the Precautionary Principle in February 2000.³⁶ At the outset, it states that it aims "to inform all interested parties, in particular the European Parliament, the Council and Member States of the manner in which the Commission applies or intends to apply the precautionary principle when faced with taking decisions relating to the containment of risk."³⁷ In addition, it seeks to develop a 'common understanding' of risk assessment, management and communication, and prevent the misuse of the precautionary principle in a protectionist manner. Should action based on the precautionary principle be deemed necessary, it ought to be proportionate, non-discriminatory, consistent with previous action, based on a cost-benefit analysis, and subject to future review.³⁸

Unquestionably, the Communication provides a useful tool for decision-making, and contributes to the ongoing debate on the issue. Yet, the Communication is "still thin on precise definition",³⁹ and fails to clarify thresholds that determine the point at which the precautionary principle is to be employed. It provides only very general guidelines, arguably so as to maintain the broad discretion of Community institutions in decision-making. Even the Economic and Social Committee, in its analysis of the Communication, concluded that the EC still needed to reach a consensus for the

³⁴ European Economic and Social Committee, 'Own-Initiative Opinion on Use of the Precautionary Principle' (2000) at page 5.

³⁵ as cited in Dratwa, J. 'Taking Risks with the Precautionary Principle: Food (and the Environment) for Thought at the European Commission' (2002) 4 *Journal of Environmental Policy & Planning* 197-213, at page 198.

³⁶ Commission of the European Communities, *Communication on the Precautionary Principle* COM 1(2000) final (EC Commission; Brussels; 2000).

³⁷ *Ibid* at page 8.

³⁸ *Ibid.* at page 3.

³⁹ Lee, R. "(Pre)Cautionary Tales: Risk, Regulation and the Precautionary Principle", in Boswall, J. and Lee, R. (eds) *Economics, Ethics and the Environment – Papers from the UKELA Cardiff Conference, June 2001* (Cavendish; London; 2001) at page 93.

meaning and application of the principle.⁴⁰ The Environment Commissioner claimed that "there is a definition...in the Communication."⁴¹ When asked what the definition was, she answered "it depends on the case it is being applied to".⁴²

To some extent, the Council Resolution passed in December 2000 modifies the operation of the precautionary principle as it was set out in the Commission's Communication.⁴³ First, whilst the Communication emphasizes the importance of risk assessment to be science-based,⁴⁴ the Resolution recognises that, if scientific knowledge is insufficient or a risk urgent, a comprehensive risk analysis might not always be feasible.⁴⁵ Second, whereas the Communication makes a distinction between scientific risk assessment and political risk management,⁴⁶ the Resolution attempts to 'socialize' the scientific process of assessment, introducing the idea of greater public participation in the identification and perception of risk.⁴⁷

Although subtle, these differences are significant in that they demonstrate that the Communication is most definitely not the 'final word'⁴⁸ on the matter, and that even during the period between the publication of the Communication in February and the passing of the Resolution in December, the boundaries of the understanding of the precautionary principle had moved. Some commentators claim that its fluctuating interpretation has repercussions on its perceived legal status. Given its variability, the identification of common traits must necessarily occur at such a high level of generality that its status is limited to guiding environmental policy, without imposing any legal obligation.⁴⁹ Hession and Macrory, for example, stress that determining the implications and legal status of the precautionary principle is largely contingent on subsequent legislative processes that seek to operationalise a framework of risk

⁴⁰ European Economic and Social Committee (2000) at page 9.

⁴¹ As cited in Bergkamp, L. 'Understanding the Precautionary Principle: Part I' (2002) Env. Liability 18, at page 18.

⁴² As cited in Stone, C. D. (2001) at page 10790.

⁴³ Vogel, D. *The New Politics of Risk Regulation in Europe* (Centre for Analysis of Risk and Regulation, London School of Economics; London; 2001) at page 16. For European Council Resolution, see Presidency Conclusions, Nice European Council Meeting 7, 8 and 9 December 2000, <u>http://europa.eu.int/council/off/conclu/dec2000/dec2000_en.htm</u>, accessed June 2003.

⁴⁴ Commission of the European Communities (2000) at section 5.1.

⁴⁵ Council Resolution, at paragraph 8.

⁴⁶ Commission of the European Communities (2000) at section 6.1.

⁴⁷ Resolution at paragraph. 20.

⁴⁸ Commission of the European Communities (2000), at section 2.

⁴⁹ See Kramer, L. EC Environmental Law (Sweet and Maxwell; London; 2000) at page 10.

assessment and precaution.⁵⁰ From this perspective, the precautionary principle under Article 174(2) is at most "an expression of political will".⁵¹

Other commentators overlook its lacking precision, focusing on its conceptual underpinnings as opposed to the manner in which it is articulated, and claiming that the principle pursuant to Article 174(2) is legally binding.⁵² Nonetheless, the extent to which the precautionary principle can derive legal status in EC law still remains unclear. Invariably, determining its status is problematic since a *principle*, unlike a *rule*, "states a reason that argues in one direction, but does not necessitate a particular direction".⁵³ By virtue of its nature, it is inherently difficult to demarcate. That said, the Commission's Communication was optimistic about its development into a binding norm of EC environmental policy. Claiming that it would be wrong to conclude that the absence of any precise definition inevitably lead to legal uncertainty, the Communication made it clear that the ambiguity of the precautionary principle would gradually evolve into specificity through the judicial process:-

"Like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision maker and *ultimately the courts* to flesh out the principle. In other words, the scope of the precautionary principle also depends on trends in case law, which to some degree are influenced by prevailing social and political values. However, it would be wrong to conclude that the absence of a definition has to lead to legal uncertainty."⁵⁴

Given this statement, it is interesting to see how the European Courts have dealt with the precautionary principle. A handful of cases have touched upon it, although the Courts have tackled neither its definition nor substance, having only outlined its

⁵⁰ Hession, M. and Macrory, R. 'Maastricht and the Environmental Policy of the Community: Legal Issues of a New Environment Policy', in O'Keeffe, D. and Twomey, P. (eds) Legal Issues of the Maastricht Treaty (Chancery; London; 1994) at pages 151-67.

⁵¹ Stallworthy, M. (2002) at page 51.

⁵² Douma, W. Th. 'The Precautionary Principle in the European Union' (2000) 9(2) RECIEL 132-143 at page 141.

⁵³ Dworkin, R. Taking Rights Seriously (Duckworth; London; 1977) at page 24.

⁵⁴ Commission of the European Communities (2000) at page 9, emphasis added.

jurisprudential background.⁵⁵ The following section introduces four early cases to illustrate the conservative approach taken by the judiciary:-

- i. Association pour la Protection des Animaux Sauvages;
- ii. The Queen v. MAFF ex parte National Farmers' Union
- iii. UK v. Commission
- iv. Bergaderm v. Commission

This section goes on to highlight four more recent judgments as a means of emphasising a shift in the judicial interpretation of precaution:-

- v. Pfizer v. Council;
- vi. Alpharma v. Council;
- vii. Monsanto Agricoltura Italia; and
- viii. The Wadden Sea Case.

While this distinction between early case law and more recent judgments aids an understanding of the development of precaution in the EC, it also reflects two very different approaches adopted by the European Courts.

4.3 Examining the case law

• <u>i. Association pour la Protection des Animaux Sauvages 56</u>

In 1992, the Administrative Court of Nantes made an Article 177 EC Treaty⁵⁷ reference to the ECJ requesting clarification on the interpretation of Article 7(4) of Directive 79/409/EEC on the conservation of wild birds.⁵⁸ Various associations for the protection of the environment had sought, before the national court, to annul the

⁵⁵ Dratwa, J. (2001) at page 4.

 ⁵⁶ Case C-435/92, Association pour la Protection des Animaux Sauvages and Others v Préfet de Maine-et-Loire and Préfet de Loire-Atlantique, 19 January 1994, ECR [1994] page I-00067.
 ⁵⁷ Now Article 234.

⁵⁸ OJ 1979 L103, page 1.

decision of the Prefects of Maine-et-Loire and of Loire-Atlantique to fix their closing dates for the hunting of migratory birds and waterfowl. The Prefects had staggered their closing dates according to migratory activity with the objective of allowing a certain percentage of the species to escape the protection granted by Article 7(4) of the Directive. The national court asked ECJ to determine whether the staggering of closing dates was compatible with the species protection afforded by the Directive.⁵⁹

Despite the fact that the ECJ did not cite the precautionary principle in its judgment, it unequivocally demonstrated precautionary approach. It held that the decision to stagger hunting closing dates was incompatible with Article 7(4) – a provision explicitly stating that dates must be fixed in a manner that guarantees the *complete* protection of migratory and wildfowl species. By *varying* the dates so as to ensure that certain number escaped protection, the Prefects of Maine-et-Loire and of Loire-Atlantique were in breach Article 7(4). The Court noted that, given that the environmental impact of the staggering of hunting dates was scientifically uncertain, it would be held to be incompatible with the Directive objective of species protection unless the Member States concerned could "adduce evidence, based on scientific and technical data relevant to each individual case"⁶⁰ that this method would not impede the *complete* protection of species. In effect, the ruling shifted the burden of proving that the practice posed no risk to the migratory birds and wildfowl before its authorisation.

ii. The Queen v. MAFF ex parte National Farmers' Union⁶¹

The National Farmers' Union, along with nine other parties involved in the raising for sale, feeding, lairage, transport and export of livestock, bovine semen, embryos and other beef-related products (hereafter collectively referred to as 'NFU') brought an action contesting various acts adopted under Article 1 of Commission Decision 96/239/EC. The Decision was implemented by the Commission subsequent to the

⁵⁹ *Ibid.* at paragraph 4.

⁶⁰ *Ibid.* at paragraph 22.

⁶¹ Case C-157/96, The Queen v Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union, and Others, 5 May 1998 ECR [1998] page I-02211.

release of two statements by the Spongiform Encephalopathy Advisory Committee ('SEAC'), an independent body that advised the UK Government in respect of the possible link between bovine spongiform encephalopathy ('BSE') and Creutzfeldt-Jakob disease ('CJD'). The Decision, based on Council Directives 90/425⁶² and 89/662, was an emergency measure against BSE imposing a temporary ban on the export of bovine animals, meat and other derived products from the UK to other Member States and third countries. During proceedings in the Queen's Bench Division of the High Court, reference for a preliminary ruling was made under Article 177 EC Treaty⁶³ questioning the validity of Article 1 of the Decision. The applicant's claims were dismissed by the CFI, and the ECJ subsequently delivered its judgment on 5 May 1998.

The NFU made three claims: that the Commission lacked the power to adopt the Decision; that the Commission misused the power to adopt that Decision; that the Decision infringed the principle of proportionality.⁶⁴

The NFU submitted that the Directives 90/425 and 89/662 did not provide an adequate legal basis for the Decision, and that, as a result, the Commission lacked the power to adopt the Decision. The NFU noted that even if the Commission did not totally lack competency, it did lack competency to prevent the export of certain bovine products because there was no material risk of BSE transmission associated with bovine semen, embryos, live calves under 6 months, fresh meat from animals under two and a half years, tallow and gelatin.⁶⁵

However, two SEAC statements sought to reclassify BSE – stating that it was no longer affecting only cattle, but should also be considered a hazard to human health.⁶⁶ SEAC claimed that there was new information suggesting that the link between BSE and CJD had ceased to be merely a theoretical hypothesis and had developed into a real possibility.⁶⁷ According to 'the most likely explanation', cases of CJD were

⁶² as amended by Council Directive 92/118/EEC of 17 December 1992.

⁶³ Now Article 234.

⁶⁴ Association pour la Protection des Animaux Sauvages and Others v Préfet de Maine-et-Loire and Préfet de Loire-Atlantique, at paragraph. 11.

⁶⁵ *Ibid.* at paragraph 16.

⁶⁶ *Ibid.* at paragraph 23.

⁶⁷ *Ibid.* at paragraph 31.

linked to contact with the BSE disease – and this required a significant modification of the perception of risk posed to human health. 68

The Court recognized that the Commission enjoyed wide discretionary powers,⁶⁹ and held that the publication of new scientific information, establishing a likely, albeit uncertain, connection between BSE and CJD, should be treated seriously. The Court concluded that the Commission did not exceed the bounds of its discretion in seeking to contain the disease within the territory of the United Kingdom by banning the export from that territory,⁷⁰ and that it was sufficiently competent to act in the way it did.

However, the NFU argued further that even if the Commission were competent to adopt the Decision, it had nevertheless misused its powers – with the main purpose of achieving an end other than that stated.⁷¹ The NFU submitted that the fifth recital in the preamble to the Decision was worded in a way that suggested that its real purpose was to allay consumer concern, and not to protect public health. Nonetheless, the Court held that, if read as a *whole*, it was evident from the text of the Decision that the Commission was prompted to invoke the provision by concerns of transmission of BSE to humans,⁷² and thus there was no misuse of powers.

The NFU's final contention was that the Decision was a disproportionate measure⁷³ given the existence of both Community and UK measures that had already been adopted. The Commission contended that the Decision was justified in the light of the uncertainties as to the potential risks to human health. The Court was of the same opinion, and stated that:-

"[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without



⁶⁸ Ibid.

⁶⁹ *Ibid*. at paragraph 39.

⁷⁰ *Ibid*. at paragraph 41.

⁷¹ see in particular, Case C-84/94 United Kingdom v Council, 12 November 1996 ECR [1996] page I-5755, paragraph 69.

⁷² Association pour la Protection des Animaux Sauvages and Others v Préfet de Maine-et-Loire and Préfet de Loire-Atlantique, at paragraph 45.

⁷³ *Ibid*. at paragraph 47

having to wait until the reality and seriousness of those risks become fully apparent."⁷⁴

Young points out that, even though this statement holds little weight, it indicates that the Court was judicially reviewing the application of the precautionary principle.⁷⁵ Although the Court did not explicitly cite the principle, it was upheld by deference to the "legislative prerogative"⁷⁶ of the Community institutions.

• <u>iii. UK v. Commission⁷⁷</u>

Also in relation to the emergency measures against BSE, the UK brought an action under Article 173 EC Treaty⁷⁸ for the suspension and ultimately the annulment of Commission Decision 96/239. The UK submitted nine pleas in total to support its application – but for the purposes of this chapter it is sufficient only to highlight the following claims: failure by the Commission to observe the limits placed on the powers conferred on it by Directives 90/425 and 89/662; misuse of powers; and breach of the principle of proportionality.

In accord with the *NFU* case, the ECJ held that the Commission's powers conferred by Directives 90/425 and 89/662 were drafted in wide terms, thus allowing the Commission to adopt the necessary safeguard measures.⁷⁹ The text of the Directives confirms that in the event of disease or any grounds likely to create a serious hazard to animals or humans, the prohibition of movement of animals and by-products from a specified territory is an appropriate measure. The Court noted that the Commission enjoyed a broad discretion as to the nature and extent of the measures it employs, and having regard to the uncertainty as to the risks to public health, the pleas alleging lacking competence and misuse of powers were rejected.

⁷⁴ *Ibid*. at paragraph 62

⁷⁵ Young, G. 'Some Thoughts on the Precautionary Principle' (2000) 1(5) Perspectives on European Business Law 16-19, at page 17.

⁷⁶ Ibid.

⁷⁷ Case C-180/96, United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities, 5 May 1998, ECR [1998] page I-02265.

⁷⁸ Now Article 230.

⁷⁹ Ibid. at paragraph 54.

Echoing the approach taken in the *NFU* case, the Court also concluded that, in the face of scientific uncertainty, the Decision was a proportionate measure, since:-

"uncertainty concerning the manner in which BSE is transmitted, particularly as regards its transmissibility through the mother, coupled with the lack of a system for tagging animals and controlling their movements, has meant that there can be no scientific certainty that the mother of a calf is completely free from BSE or, even if she is, that the calf is completely unaffected by the disease."⁸⁰

Thus, in the light of the incertitude as to the existence of risk, it was held that the emergency measure – which embodied the philosophy of precaution – was an appropriate response to the identified threat.

iv. Bergaderm v. Commission⁸¹

A similar line of reasoning was further demonstrated in the judgment of the CFI in *Bergaderm v Commission of the European Communities*. Article 4 of Council Directive 76/768/EEC concerning the approximation of the laws of Member States in relation to cosmetic products, as amended by Council Directive 93/35/EEC, required Member States to prohibit the marketing, contrary to the conditions set out, of cosmetic products containing any of the substances listed.⁸²

Laboratoires Pharmaceutiques Bergaderm produced Bergasol, a sun oil which contained 5-methoxypsoralen ('5-MOP') – a derivative of bergamot essence, suspected as potentially having carcinogenic effect.⁸³ Following the release of a number of conflicting scientific studies, the Commission sought the opinion of the Scientific Committee on Cosmetology so as to determine whether the use of the

⁸⁰ Ibid. paragraph 102.

⁸¹ Case T-199/96, Laboratoires Pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission of the European Communities, 16 July 1998, ECR [1998] page II-02805.

⁸² Annex II, and Annex III Part I to Directive 76/768/EEC.

⁸³ Laboratoires Pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission of the European Communities, at paragraph 10.

ingredient in sun oil was potentially carcinogenic. The Committee concluded that the level of 5-MOP in sun oil should be no greater than 1 mg/kg.⁸⁴ Commission Directive 95/34/EEC was subsequently invoked requiring all Member States to take necessary action to ensure that neither manufacturers nor importers could place sun creams containing more than 1 mg/kg of psoralens on the market. Bergaderm, in breach of this requirement, was formally put into liquidation, and subsequently lodged an action at the CFI on 16 July 1998 calling for the Commission to pay costs and damages.

Amid other submissions, Bergaderm claimed that the Commission manifestly erred in its risk assessment and breached the principle of proportionality.⁸⁵ In essence, the applicant argued that the Directive was adopted in the absence of any scientific evidence to prove that it was a necessary measure in order to protect the public health, and that the Directive was an inappropriate tool as a means of achieving its purported objective, namely the protection of public health.

Unsurprisingly, the Court held that since cases involving public health issues were delicate and controversial⁸⁶, the Commission must have a sufficiently wide discretion to take precautionary measures without having to wait until the reality and gravity of those risks materializes. Furthermore, the Court noted that there was no evidence to suggest that the Commission had misinterpreted the scientific reports concerning the potential risks involved in the use of bergamot essence in sun oil, and the Commission was right to refer the matter to the Scientific Committee and comply with its findings. Thus, it was held that the Commission neither made a manifest error of assessment nor adopted a disproportionate measure in the circumstances.

The language adopted in these four cases is strikingly similar, and they clearly demonstrate the Courts' limited and cautious approach to the precautionary principle in the early stages of its development. Ironically, even five years after the precautionary principle was introduced in Article 174, the term 'precautionary principle' does not feature anywhere in the text of the judgments - suggesting that the

⁸⁴ *Ibid.* at paragraph 19.
⁸⁵ *Ibid.* at paragraph 40.

⁸⁶ *Ibid*. at paragraph 55.

Courts were uneasy with its jurisprudence and uncertain of its meaning.⁸⁷ Instead, the Court *implicitly* upholds a precautionary approach behind the guise of arguments of legislative competence of the Community institutions and the doctrine of proportionality. The Court of First Instance in 2002 recognised that:-

"Prior to the enshrinement in case law of the precautionary principle, on the basis of the Treaty provisions, that principle was implicitly implied in the review of proportionality."⁸⁸

The Treaty's failure to define the precautionary principle leaves the Court with a burden of legislative proportions which it is unwilling to shoulder. As a result, the Courts have utilized the more familiar tools of judicial review to scrutinize decisions for a manifest error or a disregard for a risk of serious or irreparable damage to public health or the environment.⁸⁹ This is illustrative of schizophrenic application of precaution. Early case law demonstrates that the precautionary principle was upheld,⁹⁰ but masked behind more familiar legal jargon. The Court, without any practical direction, erred on the side of caution and handled the precautionary principle in a way more compatible with existing EC jurisprudence. This approach was understandable given the lack of legal clarity as to the meaning of the principle. Whilst the Court acknowledged the utility of anticipatory responses to uncertainty, it felt uneasy about taking the precautionary principle beyond its abstract existence and offering practical direction as to its operation.

Douma claims that it is clear from the case law that the precautionary principle can "influence or even determine the outcome of cases"⁹¹ and thus "it is preferable to describe a principle that is codified in the EC Treaty as a legally binding norm."⁹²

⁸⁷ See for example Atik, J. 'Science and International Regulatory Convergence' (1996-97) 17 Northwestern Journal of International Law & Business 736, at pages 748-9.

⁸⁸ Case T-132/00, Artegodan v Commission of the European Communities, 26 November 2002 ECR [2002] page II-04945, paragraph 185. Court refers to Case C-180/96 United Kingdom v Commission of the European Communities paragraphs 73-78; Order of the President of the Court of First Instance in Case T-76/96 National Farmers' Union and Others v Commission of the European Communities [1996] ECR II-815, paragraphs 82-93, in particular paragraph 89.

⁸⁹ Young, G. (2000) at page 19; see also Douma, W. Th. (2000) at page 137.

⁹⁰ This was confirmed by the CFI in 2002 in Case T-70/99, Alpharma Inc. v Council of the European Union, 11 September 2002, ECR [2002] page 00000, at paragraph 152.

⁹¹ Douma, W. Th. (2000) at 141.

⁹² Ibid.

However, it is difficult to conclude from these cases that the precautionary principle was legally binding in its own right since it was never explicitly referred to, and influenced the outcome of the cases only insofar as the existing jurisprudential framework allowed. Nevertheless, more recent judgments suggest an elevation of the status of the precautionary principle. The following section introduces four cases which illustrate increasing judicial confidence in the interpretation and application of Article 174(2).

4.4 A different approach

v. Pfizer⁹³

Additives to animal foodstuffs such as vitamins, trace elements, binders, preservatives, coccidiostats and antibiotics are controlled by Directive 70/524/EC which was last substantially amended by Directive 96/51/EC. Only additives on an authorized list can be used in animal feeds subject to certain conditions of use. Under the legal provisions, a Member State is able to prohibit the use of an additive if it is thought to create a risk to animal or human health or the environment.

In the light of advice from a national scientific body, Denmark banned the use of virginiamycin, belonging to the streptogramin class of antibiotics, in animal foodstuffs. The Commission subsequently sought scientific advice from the Scientific Committee for Animal Nutrition ('SCAN'), and on 17 December 1998, relying on the Commission's guidance, the Council adopted Regulation 2821/98 banning the use of four antibiotics – virginiamycin, bacitracin zinc, spiramycin, and tylosin phosphate – as additives in animal foodstuff because of concerns of the development of animal resistance to antibiotic and transmission of resistance to humans through consumption.

The contested Regulation was adopted by the Council on the basis of Article 11(3) of Directive 70/524 - enabling the Commission to instigate an Article 24 procedure to

⁹³ Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, 11 September 2002, ECR [2002] page 00.

alter the lists of authorized antibiotics in response to concerns raised by a Member State in respect of the protection of human or animal health, or the environment. Relying upon Article 3a(e) of the Directive,⁹⁴ the Council withdrew authorization for the use of 4 antibiotics as additives in foodstuffs, claiming that, in relation to virginiamycin in particular, its decision was justified because there was a risk that the effectiveness of certain human medicines could be jeopardized.⁹⁵

Pfizer Animal Health SA ('Pfizer'), the only producer of virginiamycin when the regulation was adopted, lodged an application at the CFI challenging the legality of the provision.⁹⁶ Pfizer argued that there were eight grounds for annulment - inevitably making this case exceedingly complex – although its principal claims were that the Community institutions erred firstly, in their assessment and management of the possible risks to human health posed by the use of virginiamycin in animal foodstuffs, and secondly, in their application of the precautionary principle.⁹⁷

Both parties agreed that Directive 70/524 permitted Community institutions to adopt a measure on the basis of the precautionary principle, although they disagreed on the interpretation of precaution, and the relationship between precaution and scientific risk assessment.⁹⁸

Pfizer and the Council accepted that the measure prohibiting the use of virginiamycin could not legitimately be based on a 'zero risk' test – since it is impossible to prove conclusively that a particular substance creates zero risk to human health, either now or in the future.⁹⁹ However, Pfizer argued that the Community institutions were prohibited from invoking precautionary measures unless and until they had

"does not require an activity to be prohibited or subjected to draconian restrictions whenever it cannot be scientifically proved that there is absolutely no risk attaching to it, since it is common knowledge that lawyers have always described proving a negative as *probatio* diabolica and not without reason."

⁹⁴ See Recital 5 of Regulation (EC) No. 2821/98.

⁹⁵ Ibid. at Recital 21.

⁹⁶ Note, an interim application to market the product pending appeal was rejected.

⁹⁷ Pfizer Animal Health SA v Council of the European Union, at paragraph 108.

⁹⁸ *Ibid*. at paragraph 113.

⁹⁹ Ibid. at paragraph 130: A zero risk test, according to the Court, would "quickly lead to the paralysis of technological development and innovation." This point was reiterated in case C-6/99, Association Greenpeace France v Ministere de l'Agriculture et de la Peche [2000] ECR page I-1651, in which the Court (at paragraph 72) claimed that the precautionary principle:-

undertaken a *full* scientific assessment of the potential risks, and had shown that any such risks are probable.¹⁰⁰ Although it acknowledged that virginiamycin *may* create a 'hazard to human health', Pfizer submitted that this is an unsatisfactory ground upon which to base the Regulation. Instead, Pfizer required that a higher threshold of proof be imposed, stating that:-

"[i]t would be proven with *the first dead man*. It would be proven with the first infection, or with the first proof of colonization, or the first proof of transfer in a human."¹⁰¹

The Court held that Pfizer's interpretation of the precautionary principle was incorrect:-

"it must be borne in mind that, when the precautionary principle is applied, the fact that there is scientific uncertainty and that it is impossible to carry out a full risk assessment in the time available does not prevent the competent public authority from taking preventive protective measures if such measures appear essential, regard being had to the level of risk to human health which the public authority has decided is the critical threshold above which it is necessary to take preventive measures."¹⁰²

Overall, the Court found in favour of the Council, concluding that it neither made manifest errors of risk assessment and management nor breached the precautionary principle. In its lengthy judgment, the Court endeavoured to shed light on the role played by the precautionary principle in the risk assessment processes. The Court held that the application of the precautionary principle was permitted in situations where there existed a risk to human health, even if the risk could not be fully demonstrated.¹⁰³ It also decided that precaution could not be based on a purely

¹⁰⁰ *Ibid.* at paragraphs 129-130.

¹⁰¹ Ibid. at paragraph 379, emphasis added.

¹⁰² *Ibid*. at paragraph 382.

¹⁰³ Paragraph 144.

hypothetical approach to risk.¹⁰⁴ There had to be tangible scientific evidence of the magnitude and likely occurrence of the threat.¹⁰⁵

In its approach to precaution and risk assessment, the CFI placed scientific enquiry at the heart of precautionary decision-making, stating that:-

"Scientific advice is of the utmost importance at all stages of the drawing up and implementation of new legislation and for the execution and management of existing legislation. The duty imposed on the Community institutions by the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection means that they must ensure that their decisions are taken in the light of the best scientific information available and that they are based on the most recent results of international research."¹⁰⁶

Furthermore, although it noted that a full scientific assessment of potential hazards might not always be possible, the Court held that the application of precaution must be adequately supported by scientific data¹⁰⁷ This affiliation between precaution and risk assessment was maintained by the CFI in *Alpharma*.

• <u>vi. Alpharma¹⁰⁸</u>

In conjunction with the *Pfizer* case, an application was made by Alpharma in relation to the withdrawal of bacitracin zinc as an additive to animal foodstuffs pursuant to Council Regulation 2821/98. Recital 22 to the contested regulation states that:-

"selected resistances from the use of bacitracin zinc as a feed additive inevitably increase the reservoir of resistance to bacitracin zinc", and that "these resistances could be transferred from animals to humans and reduce

¹⁰⁴ *Ibid*.

¹⁰⁵ *Ibid*.

¹⁰⁶ *Ibid.* at paragraph 5.

¹⁰⁷ *Ibid.* at paragraph 144.

¹⁰⁸ Case T-70/99, Alpharma Inc. v Council of the European Union, 11 September 2002, ECR [2002] page 00000.

the effectiveness of bacitracin zinc used as a human medicinal product."¹⁰⁹

Alpharma claimed that the Court should annul the Regulation, either in its entirety or in so far as it concerns bacitracin zinc, and order the Council to pay costs.

The arguments of Alpharma were largely comparable with those submitted in Pfizer. Alpharma submitted four pleas: i) breach of essential procedural requirements; ii) manifest errors of assessment, which included errors in the risk assessment, and in the application of the precautionary principle; iii) infringement of fundamental principles of Community law, namely, the principles of proportionality and protection of legitimate expectations; and iv) breach of the obligation to state reasons.¹¹⁰

It was clear from recital 29 to the contested regulation that the Council relied on the precautionary principle to justify its adoption.¹¹¹ Alpharma accepted that the precautionary principle enabled Community institutions to quickly adopt pre-emptive measures in the face of an emergency, but argued that the principle could not be used as an excuse for failing to carry out a sufficiently thorough risk assessment.¹¹² Alpharma maintained that the Community institutions made a manifest error of assessment in concluding that they had sufficient cogent and reliable scientific evidence to suggest a link between the use of bacitracin zinc and animal and human resistance. Contrary to the course of action in *Pfizer*, the Community institutions in this case authorized the withdrawal of bacitracin zinc without first obtaining a scientific opinion from SCAN regarding the associated risks.¹¹³ Despite this, the Court found that Alpharma had failed to demonstrate that the Community institutions had erred in their risk assessment, and although scientific knowledge at the time was incomplete, it was clear that the Council could reasonably conclude that there existed serious human health concerns.¹¹⁴

¹⁰⁹ *Ibid.* at paragraph 271.
¹¹⁰ *Ibid.* at paragraph 99.

¹¹¹ *Ibid.* paragraph 134. Recital 29 states that "the prohibition on the use of the antibiotics bacitracin zinc, spiramycin, virginiamycin and tylosin phosphate ought to be perceived as an interim protective measure taken as a precaution".

¹¹² *Ibid.* at paragraph 148.

¹¹³ *Ibid*. at paragraph 203.

¹¹⁴ *Ibid*. at paragraph 313.

A considerable part of the *Alpharma* judgment was devoted to outlining the role of the precautionary principle in processes of risk assessment.¹¹⁵ In line with the *Pfizer* decision, the Court noted that the precautionary principle was intended only to apply in situations in which it had been proven by scientific means that a risk was more than merely hypothetical.¹¹⁶

Although it has been acknowledged that the precautionary principle has not yet been fully defined in EC case law,¹¹⁷ *Pfizer* and *Alpharma* chart the further development of precautionary jurisprudence and provide the precautionary principle with both form and substance. Both cases insinuate an elevation of the status of the precautionary principle beyond a pure policy tool to a legally binding norm that is open to challenge, and we see the manifestation of more concrete principles upon which the Courts might base that contention.

In contrast with the four early cases, and in response to the Commission's instruction to the Courts to flesh out its definition, *Pfizer* and *Alpharma* illustrate increasing recognition of the precautionary principle in its operational context, and if nothing else, provide a stepping stone to further understanding of its utilisation within the EC. It has been interesting to see whether the Courts have continued to take a proactive role in interpreting precaution. The following two cases illustrate the way in which, in the aftermath of *Pfizer* and *Alpharma*, the ECJ has been increasingly willing to develop a practical framework in which precaution can operate.

vii. Monsanto Agricoltura Italia¹¹⁸

By virtue of Regulation 258/97, foods produced from genetically modified organisms, but which no longer contain them, may be placed on the market *without* prior authorization, provided a national food assessment body has certified that the novel food is substantially equivalent to the traditional non-GM food already being

¹¹⁵ Ibid. at paragraph 152-184.

¹¹⁶ *Ibid.* at paragraph 159.

¹¹⁷ Opinion of Mr Advocate General Alber, Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others [2003] ECR page I-08105, at paragraph 135.

¹¹⁸ Case C-236/01, Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, 9 September 2003 [2003] ECR page I-08105.

marketed. According to the provisions contained in the Regulation, the person responsible for the placing on the market is under an obligation to notify the Commission.¹¹⁹ In 1997 and 1998, after the approved food authority had certified substantial equivalence, Monsanto Europe SA and two other firms used the simplified procedure to notify that foods made from genetically modified maize were being placed on the market.¹²⁰

Between November 1998 and April 1999, the Italian Health Ministry wrote to the Commission requesting reports of toxicological and allergenicity assessments conducted in relation to GM maize produced by Monsanto.¹²¹ Instead of replying directly to the letters, the Commission, in accordance with its practice, forwarded the information to Monsanto and the two other firms for them to make that information immediately available to the Member States. The Italian Republic claimed that the absence of detailed information, and in particular, the renewed interest by the Scientific Committee for Food, provided adequate grounds for the precautionary suspension of the marketing and use of transgenic products. On 4 August 2000, pursuant to Article 12 of Regulation, the Italian Republic adopted a Decree¹²² prohibiting the marketing pf foods made from genetically modified maize which were authorized using the 'simplified procedure'. Monsanto (and others) challenged the During proceedings, the Tribunale Amministrativo Regionale de Lazio Decree. referred to the ECJ questions in relation to (i) the admissibility of the simplified procedure in the light of evidence that the foods contained residues of transgenic protein; (ii) the compatibility of procedure with Articles 153 and 174 EC Treaty; and (iii) the degree to which the simplified procedure took account of the precautionary principle. For the purposes of this section, the third question warrants further examination.

¹¹⁹ Article 5, Regulation 258/97.

¹²⁰ Simplified procedure set out in Article 5: 'In the case of the foods or food ingredients referred to in Article 3(4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the relevant details provided for in Article 3(4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the "C" series of the Official Journal of the European Communities."

¹²¹ Case C-236/01, Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, [2003] ECR 00, at paragraph 25.

¹²² The Prime Ministerial Decree of 4 August 2000, which suspended the marketing and use of products derived from transgenic maize of the lines Bt-11, MON 810 and MON 809.

In his Opinion, Advocate General Alber offered an explanation of the precautionary principle, suggesting that even a *theoretical* risk might justify precautionary action. Accordingly, conclusive evidence of the reality of the risk was "not required",¹²³ and precautionary action was deemed appropriate even where the cause for concern was "based on preliminary scientific findings."¹²⁴ Precautionary action was deemed to be justifiable when "no *concrete threat to those resources has yet been demonstrated* but initial scientific findings indicate a *possible* risk."¹²⁵

The Advocate General considered that the simplified procedure adequately accounted for the protection of health and the precautionary principle.¹²⁶ The ECJ adopted a similar stance, concluding that Regulation 258/97 already contained provisions upholding the notion of precaution.¹²⁷ In particular, the Court explained that the safeguard clause contained in Article 12 "must be understood as giving specific expression to the precautionary principle"¹²⁸ Article 12 required that Member States wanting to temporarily restrict or suspend the trade in, and use of, a particular food, or food ingredient, provide details that it posed a danger to human health or the environment, and immediately inform other Member States and the Commission.¹²⁹ The Commission is obliged to present a draft of those grounds to the Standing Committee for Foodstuffs,¹³⁰ which, following detailed examination, will deliver its opinion on the draft within a time limit specified by the Committee Chairman.¹³¹ The Commission shall adopt the measure if it is in accordance with Committee opinion.¹³² However, if the measure is not in accordance with Committee opinion, or the Committee gives no opinion, the Commission is obliged to submit a proposal relating to measure to the Council.¹³³ The Council shall act by gualified majority,¹³⁴ and, if it

¹²³ Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, Opinion of the Advocate General, at paragraph 137.

¹²⁴ Ibid.

¹²⁵ *Ibid.* at paragraph 108, emphasis added.

¹²⁶ Ibid at paragraph 202.

¹²⁷ Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, ECJ Judgment, at paragraph 112.

¹²⁸ *Ibid.* at paragraph 110.

¹²⁹ Regulation No. 258/97, Article 12(1).

¹³⁰ *Ibid*. Article 12(2).

¹³¹ *Ibid*, Article 13(3).

 $^{^{132}}$ *Ibid*, Article 13(4)(a).

 $^{^{133}}$ *Ibid*, Article 13(4)(b).

¹³⁴ *Ibid*, Article 13(4)(b).

fails to do so within three months of referral, the proposed protective measure shall be adopted by the Commission.¹³⁵

According to the ECJ, the procedural requirements set out in Article 12 had enshrined the spirit of the precautionary principle, and thus the claim by the Italian Republic that the simplified procedure conflicted with the precautionary principle was erroneous. In reaching this conclusion, the Court adopted what is described as a 'deferential' approach – that is, it referred to the EC Regulation and concluded that the precautionary principle had already been upheld.¹³⁶

This deference to Community provisions emerges from the broad discretion given to policy-makers.¹³⁷ During proceedings for an Article 234 reference for preliminary ruling, Advocate General Mischo noted that:-

"Since that principle is to be applied in situations of great uncertainty, we cannot expect the courts to impose their own convictions, the possible basis of which is difficult to discern, moreover, in the realm of scientific problems.

It is obviously not a question of removing the application of the precautionary principle from the sphere of judicial review, but merely of recognising that the courts can, in this field, only exercise minimal review since the political authorities must be granted a broad discretion."¹³⁸

¹³⁵ Ibid.

 $^{^{136}}$ Similarly, the ECJ in Case C-6/99, *Greenpeace v Ministère de l'Agrulture et de la Pêche* [2000] ECR page I-01655, held (at paragraph 44) that observance of the precautionary principle was already reflected in the obligations created by Article 11 of Directive 90/220 on the deliberate release into the environment of genetically modified organisms. Article 11 imposed a duty on the manufacturer or importer to the Community to, before a GMO was placed on the market as or in a product, submit a notification to the competent authority of the Member State where the product is to be placed on the market, outlining an assessment of potential risks to human health or to the environment.

 ¹³⁷ This discretion is subject to the requirement that the protection of pubic health and of the environment takes precedence over economic interests, and the principles of proportionality and non-discrimination: see case T-132/00, Artegodan v Commission of the European Communities [2002] ECR page II-04945, at paragraph 186.
 ¹³⁸ Case C-241/01, National Farmers' Union v. Secrétariat général du gouvernement [2002] ECR page

¹³⁸ Case C-241/01, National Farmers' Union v. Secrétariat général du gouvernement [2002] ECR page I-09079, at paragraphs 74 and 75. For further discussion of this deference to the legislative prerogative to Community institutions, see Young, G. (2000) at page 17.

One practical implication of this discretion is the resultant ambiguity relating to the degree of scientific certainty required before precautionary responses are instigated. From this perspective, the question of when the precautionary principle applies becomes just as important as *what* the precautionary principle entails. Determining its point of application depends on its relationship with scientific risk assessment. As the following section illustrates, judicial interpretations of the precautionary principle signal a shift in the way in which this relationship has been perceived.

4.5 An emerging pattern?

There are cases to suggest that a precautionary measure cannot properly be based on a 'purely hypothetical approach to risk'.¹³⁹ An explicit connection is made between precaution and risk assessment,¹⁴⁰ and the precautionary principle is perceived as applying after a thorough scientific investigation of the likely magnitude and occurrence of an expected threat.¹⁴¹ Its operation depends on there being tangible scientific evidence of the existence of a risk. The application of the precautionary principle cannot be founded "on a mere conjecture which has not been scientifically verified."¹⁴² A scientifically-certain risk is necessary before precautionary responses are triggered. More recent cases, however, have suggested that the application of the precautionary principle can precede the ascertainment of a scientifically-certain

¹³⁹ See Case E3/00, EFTA Surveillance Authority v Kingdom of Norway [2001] paragraphs 36-38. ¹⁴⁰ See, for example, Case C-41/02, Commission v. Kingdom of the Netherlands, in which the Court states (at paragraph 53) that:-

[&]quot;[a] proper application of the precautionary principle requires, in the first place, the identification of the potentially negative consequences for health of the proposed addition of nutrients, and, secondly, a comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research."

See also, Pfizer Animal Health SA v Council of the European Union, in which the CFI states (at paragraph 5) that a scientific risk assessment is required before any anticipatory action is taken; and the Opinion of Mr Advocate General Mischo, Case C-192/01, Commission v. Denmark [2003] ECR page I-09693, at paragraph 114.

¹⁴¹ Case C-192/01, Commission of the European Communities v Kingdom of Denmark, Opinion of Advocate General Mischo,23 September 2003, ECR [2003] page I-09693, at paragraph 102. ¹⁴² Pfizer Animal Health SA v Council of the European Union, at paragraphs 143 and 145.

threat.¹⁴³ From this perspective, the principle is seen as coming into effect *before* the existence and gravity of risk can be established using risk assessment processes.¹⁴⁴

• viii. The Wadden Sea Case¹⁴⁵

One of the most recent declarations by the European Courts that the precautionary principle might operate before the impact of a risk has been verified came about during a ruling by the ECJ on a preliminary reference made by the Raad van State. In the *Wadden Sea* case, the ECJ was asked to determine when an 'appropriate assessment' under Article 6(3) of the Habitats Directive¹⁴⁶ should be conducted.¹⁴⁷ An appropriate assessment was construed as a manifestation of precaution. It was not clear under if, before conducting an appropriate assessment, it was necessary to ascertain that a significant effect had already ensued, or whether it was sufficient merely to establish that it was *not unlikely* that a significant effect *might* materialise.

In its clarification of the issue, the ECJ appealed to the precautionary principle, describing it as 'one of the foundations of the high level of protection pursued by Community policy'.¹⁴⁸ Drawing on the implications of the principle, the ECJ concluded that an appropriate assessment was to be conducted if the risk of significant

¹⁴³ Commission of the European Communities v Kingdom of Denmark, at paragraph 101; Bergaderm SA v Commission of the European Communities, at paragraph 66.

 ¹⁴⁴ Case C-24/00 Commission of the European Communities v France, 5 February 2004, ECR [2004] page 00, at paragraph 56.
 ¹⁴⁵ Case C-127/02, Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging

¹⁴⁵ Case C-127/02, Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging tot Bescherming van Vogels v Staatssecretaris van Landbouw, Natuurbeheer en Visserij, 7 Septmber 2004, ECR [2004] page 00.

¹⁴⁶ Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ 1992 L206, page 7.

¹⁴⁷ Article 6(3) reads as follows:-

[&]quot;Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives. In the light of the conclusions of the assessment of the implications for the site and subject to the provisions of paragraph 4, the competent national authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public."

¹⁴⁸ Landelijke Vereniging tot Behoud van de Waddenzee and Nederlandse Vereniging tot Bescherming van Vogels v Staatssecretaris van Landbouw, Natuurbeheer en Visserij, 7 Septmber 2004, ECR [2004] page 00, at paragraph 44.

effect 'cannot be excluded on the basis of objective information'.¹⁴⁹ The Court went on to explain that this meant that an assessment should be carried out where there is 'doubt as to the absence of significant effects'.¹⁵⁰ In the light of this interpretation, Article 6(3) should not be interpreted as requiring that an assessment is performed if a plan or project is considered to *definitely* have significant effect on a site.¹⁵¹ An appropriate assessment is required when there is a '*mere probability*' of a significant effect.¹⁵²

It is interesting to note the way in which the ECJ handled the precautionary principle in this case. Although, on the whole, little reference was made to the principle, it is certainly clear that when the Court *did* endeavour to explain its relationship with Article 6(3) of the Habitats Directive, it adopted a markedly different approach to past judicial treatment of precaution. In order to illustrate the profundity of its new tactic, it is useful to consider it in the context of previous judgments. Only after doing so will it become evident that the European Courts are gradually liberalising the threshold of precaution - meaning that they are becoming increasingly willing to extend its scope of application, broadening the meaning of 'uncertainty' in relation to which the precautionary principle operates. The rationale for this shift has not been made explicit. However, it is reasonable to suggest that the Courts, in view of public confidence crises over concerns such as Bovine Spongiform Encephalopathy, salmonella, hormone-treated meat, genetically modified organisms, the Sars virus, and bird flu, are making a more fervent statement recognising that science cannot always predict the occurrence and magnitude of future hazards. Instead of requiring, before the application of precaution, the scientific verification of future events, the Courts are demonstrating a willingness to require the application of precaution before a risk is scientifically established.

The ECJ in the *Wadden Sea* case construed the precautionary principle as applying where there was doubt as to the absence of environmental degradation,¹⁵³ and where uncertainty of a hazardous impact 'could not be excluded' on the basis of objective

¹⁴⁹ Ibid.

¹⁵⁰ Ibid.

¹⁵¹ *Ibid.* at paragraph 41.

¹⁵² Ibid.

¹⁵³ Ibid.

information.¹⁵⁴ Later on in the judgment, the Court noted that the precautionary principle would only *not* apply if the competent authority had '*made certain*' that the plan or project would not adversely affect the integrity of the site concerned.¹⁵⁵ Given the impossibility of predicting *with certainty* that a plan or project would not impair the environment, the precautionary principle became, in effect. perpetually applicable. Whereas the CFI in *Pfizer* limited its application to scientifically verified risk, the Court in *Wadden Sea* effectively extended the operation of the precautionary principle *all future uncertainty*, irrespective of scientific testimony. The ECJ replicated the *Wadden Sea* approach towards the end of 2004 when it commented that the precautionary principle is applicable in circumstances:-

"[w]here it proves to be impossible to determine *with certainty* the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures."¹⁵⁶

This stance is significant. Not only does it illustrate the Courts' increasing readiness to allude to the precautionary principle, but it also signals a new ethos in which they are willing to push the boundaries of its application. Instead of relying on scientific corroboration of the possibility of a risk, the Courts are implicitly beginning to recognise the prevalence of future uncertainty and the inability of science to comprehend that which has not yet materialized.

Underlying this change in judicial perception of the future is a conceptual shift from a discourse based on the notion of *quantifiable* risk to a discourse focusing on numerically *indeterminate* uncertainty.¹⁵⁷ It represents an attempt, at least, to free environmental decision-making from the shackles of scientific knowledge, and to

¹⁵⁴ Case C-41/02, Commission of the European Communities v Kingdom of the Netherlands, 2 December 2004, ECR [2004] page 00, at paragraph 44.

¹⁵⁵ Ibid. at paragraph 59, emphasis added.

¹⁵⁶ Commission of the European Communities v Kingdom of the Netherlands, at paragraph.54.

¹⁵⁷ This conceptual distinction between risk and uncertainty is based on the seminal work of Frank Knight. See Knight, F.H. *Risk, Uncertainty and Profit* (Houghton Mifflin Company; Boston; 1921)

concede to the fallibility of scientific prophecies of unknown consequences.¹⁵⁸ However, the ability of precautionary measures in the face of uncertainty to provide a more suitable 'cognisance of the future'¹⁵⁹ than scientific prediction depends entirely on the willingness of decision-making institutions, first, to detach themselves from their deeply embedded positivist, rational, scientific traits; and second, to recognise that responsibility for decision-making about future hazards is more easily attributed if those decisions are made on *moral*, rather than scientific, grounds. Only *after* a complete shift in the institutional mindset has occurred is the precautionary principle likely to have substantive implication. Pending any transformation, however, and despite the latest judicial propensity to disengage the application of precaution from scientific assessment, the point at which the precautionary principle is applicable remains a tentative issue.

Determining the relationship between the precautionary principle and scientific means of prediction lies at the heart of any inquiry into the meaning and implication of precaution. As Part Two of this thesis illustrates, the ideological underpinnings of scientific risk assessment raise fundamental questions about the ability of the precautionary principle to secure responsibility for the latent impact of environmental hazards. The following section focuses on the affiliation between science and precaution, as it is perceived in the EC framework of human health protection. It shows that, on a procedural level, the precautionary principle is seen as championing scientific expertise.

4.6 The precautionary principle in the EC – a scientific tool

Despite being conceptually rooted in an increasing distrust of the ability of scientific expertise to predict the occurrence and magnitude of risks to human health and the environment, the precautionary principle in the EC regulatory administration is

¹⁵⁸ See D. Parr 'Knowing About Ignorance', in T. Gilland *et al*, *Debating Matters: Science: Can We Trust the Experts?* (Hodder & Stoughton; London; 2002) Essay 4, at page 55.

¹⁵⁹ B. Adam 'Re-Vision: The Centrality of Time for an Ecological Social Science Perspective', in S. Lash, B. Szersynski, and B. Wynne (eds), *Risk, Environment and Modernity – Towards a New Ecology* (Sage Publications; London; 1996) chapter 3.
definitely scientifically-based.¹⁶⁰ The underlying assumption is that modernity and its associated technological advances pose threats of which we are unaware, and in order to avoid future harm we need to regulate more stringently. Thus, the tendency of EC institutions to treat the precautionary principle as a scientific tool indicates recognition of the need to improve and intensify risk assessment and support decision making with scientific fact. In an age of growing pressure to hold decision-makers to account, marked by a rise in the judicial review of regulatory decisions at EC level, the 'hard facts' of science are increasingly being relied upon to transfer responsibility for otherwise uncorroborated conduct. The consequence is the emergence in the EC legal order of a paradoxical pattern. Whilst the precautionary principle is perceived as a challenge to the value of scientific information in insuring against future harm, the legitimacy of anticipatory decision-making is measured against yardstick of scientific fact. In the EC, at least, this conflict has been resolved by the portrayal of precaution as a scientific instrument.

In 1997, the *Green Paper on General Principles of Food Law in the EU* noted that, in order to ensure a high level of protection of health and the environment, measures should be based on a risk assessment "taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods."¹⁶¹ This scientific emphasis was echoed by the Commission's Communication on the Precautionary Principle in 2000, which stated that scientific data relevant to the risks must always be evaluated *before* the application of the precautionary principle.¹⁶²

To some extent, this drive to ensure that scientific knowledge is given a pivotal role in decision-making has been stimulated by a marked increase in public distrust of scientific authority. This issue was central to the White Paper on Food Safety,¹⁶³ published in 1999, which recognised that:-

¹⁶⁰ Vogel, D. (2001) at page 17.

¹⁶¹ COM(97) 176, 30 April 1997.

¹⁶² Commission of the European Communities, *Communication on the Precautionary Principle*, at page 13, emphasis added.

¹⁶³ COM(1999)719 final.

"[f]ood safety needs to be organized in a more co-ordinated and integrated way ... The European Union needs to re-establish public confidence in its food supply, its food science, its food law and its food controls."¹⁶⁴

It is interesting that, in an attempt to restore consumer confidence in scientific expertise, the Commission should call for a *more* scientific response to food safety concerns rather than exposing scientific domain to public scrutiny and participation. This can, perhaps, be explained using the words of Luhmann – that "[s]cience can escape the risk of loss of authority ... only by inducing it itself."¹⁶⁵

The deliberate effort to give regulatory decision-making a more rigorous scientific basis is evident in the founding of the European Food Safety Authority (EFSA). Having been provisionally set up in Brussels in 2002, the EFSA was legally established by Regulation No.178/2002.¹⁶⁶ The Regulation stated that the EFSA would facilitate the centralisation of risk assessment so as to avoid the fragmentation of the internal market,¹⁶⁷ and provide a "strong scientific base" for regulatory decision-making.¹⁶⁸ Its principal objective was referred to in the Preamble as ensuring that "consumers, other stake-holders and trading partners have confidence in the decision-making process, its scientific basis and the structures and independence of the institutions protecting health and other interests."¹⁶⁹ Essentially its role was to provide an independent scientific point of reference in risk assessment, and in so doing, assist in ensuring the smooth functioning of the internal market.¹⁷⁰

However, the establishment of the EFSA – as an attempt to counteract diminishing consumer confidence – is based on an unsound assumption. It ignores the fact that declining faith in scientific enterprise is not so much to do with the accuracy of scientific evidence, but rather is a response to the nature of the process through which that evidence is obtained. The formal separation, which the EFSA achieves, between science and 'everything other than science' denies that science is, in fact, a social

¹⁶⁴ Ibid. paragraphs 6-7; see also chapter 4: 'Towards Establishing a European Food Authority'.

¹⁶⁵ Luhmann, N. Risk: A Sociological Theory (Gruyter; 1991) at page 215.

¹⁶⁶ Regulation No.178/2002 of 28 January 2002, OJ L31 1 February 2002.

¹⁶⁷ *Ibid.* at Preamble, paragraph 34.

¹⁶⁸ *Ibid.* at Article 1(1).

¹⁶⁹ *Ibid.* at Preamble, paragraph (9).

¹⁷⁰ *Ibid.* at Preamble, paragraph 34.

process. By presenting itself as an independent scientific risk assessor, the EFSA is, in effect, making an explicit statement that scientific process is a self-governing and objective sphere. Yet, as a number of theorists have argued, consumer distrust in scientific expertise is likely to remain for long as it operates without broader contextual analysis and stakeholder participation.¹⁷¹

A further consequence of the shift in emphasis to scientific knowledge subsists in relation to the conceptual underpinnings of the precautionary principle. In laying particular emphasis on scientific evidence in risk assessment, the precautionary principle is transformed from being a decision-making tool in its own right, to an integral component of *scientific* process. However, as Adams fittingly points out, the linking of the precautionary principle back to risk and scientific evidence in many ways:-

"undermines the very reasons why international agreements call for action to be based on precaution in the first instance, namely that scientific uncertainty surrounding many environmental problems emphasizes that risk cannot always be quantified and evidence isn't always available."¹⁷²

Ultimately, the EFSA model, in its portrayal of scientific assessment as an objective and authoritative process, promotes the notion that risk assessment prescribes specific precautionary responses to the future. Both the explicit reliance of risk assessment on exclusively-scientific evidence and the contention that science operates as an

¹⁷¹ There is a large body of literature relating to public participation in decision-making relating to risk. The broad argument is that increased participation improves dialogues, builds trust, and enhances transparency. For detailed discussion, see Walker, G. *el al* 'Risk Communication, Public Participation and the Seveso II Directive' (1999) 65 Journal of Hazardous Materials 179-190; Irwin, A. 'Regulatory Science – Towards a Sociological Framework' (1997) 29(1) Futures 17-31, at page 28; and Irwin, A. 'Constructing the Scientific Citizen: Science and Democracy in the Biosciences' (2001) 10 Public Understanding of Science 1-18, particularly page 15, which advocates greater public dialogue and engagement in regulatory decision making; Royal Commission on Environmental Pollution, Setting Environmental Standards, 21st Report (HMSO; London; 1998) at page 102:-

[&]quot;Those directly affected by an environmental matter should always have the accepted right to make their views known before a decision is taken about it. Giving them that opportunity is also likely to improve the quality of decisions; drawing on a wider pool of knowledge and understanding (lay as well as professional) can give warning of obstacles that, unless removed or avoided, would impede effective implementation of a particular decision".

¹⁷² Adams, M.D. (2002) at page 307.

autonomous sphere give rise to an understanding not only that legitimate predictions of hazardous events must be scientifically formulated, but also that there can only be one 'proper' application of the precautionary principle, predetermined on the basis of scientific foresight. And, although the EFSA risk assessment is still in its initial stages of development, it is indicative of the institutional treatment of the relationship between the notion of precaution and scientific discourses. Furthermore, it denotes the propensity to regard the precautionary principle as a cast-iron concept. This idealistic practice, however, is inconsistent with the argument that the precautionary principle is contextually-framed. As it is illustrated in Chapters Six to Nine, the socially-constructed backdrop to the implementation of the precautionary principle is critical to its interpretation.

Chapter Five

The Precautionary Principle in the UK

5.0 Introduction

In the words of O'Riordan:-

"A decade ago, precaution was a dirty word. It was treated with great suspicion by the UK government, because it was regarded as a costraising, time-delaying and benefits-reducing measure."¹

Although the precautionary principle has since come to be accepted as part of the domestic environmental agenda, the development of precaution in the UK has been far less momentous than in international and EC spheres. There are certainly fewer examples of its use in policy documents, and the judiciary have been less inclined to perceive it as a free-standing principle.² There are arguments that, in the light of evidence that precaution is "too rarefied for the English judicial palate",³ it should be interpreted as a procedural, rather than substantive, requirement. Elizabeth Fisher has written extensively in this area, arguing that the definitional implications of the precautionary principle can be overcome by construing it in terms of procedural fairness.⁴ This provides an excellent explanation for the more passive approach of English Courts, and suggests that the languid evolution of the precautionary principle in the UK can be seen as consequence of the common law tradition. In Germany, for example, the notion of precaution has long been interpreted as a central tenet of administrative law, securing consistency, predictability, transparency, and accountability in decision-making.⁵ By contrast, and as a result of the common law

¹ O'Riordan, *Foreword*, in Harremoës. P. *et al* (eds) The Precautionary Principle in the 20th Century – Late Lessons from Early Warnings (Earthscan Publications Ltd; London; 2002) at page xi.

 ² See, for example, the judgment of Richards J. in R. v Leicestershire County Council ex parte Blackfordby and Boothorpe Action Group Ltd. [2001] Environmental Law Reports 2, at paragraph 65.
 ³ Beloff, M. 'Judicial Review: 2001 – A Prophetic Odyssey' (1995) 58 MLR 143 at page 153.

⁴ Arguably, Fisher's seminal piece in this area is: Fisher, E. 'Is the Precautionary Principle Justiciable?' (2001) 13(3) *Journal of Environmental Law* 315-334.

³ See, for example, Boschert, K. and Gill, B. 'National Report: Germany. Precaution for Choice and Alternative' (Ludwig-Maximilians-Universität; München; 2004) at page 6. See also De Sadeleer, N. 'The Enforcement of the Precautionary Principle by German, French and Belgian Courts' (2000) 9(2)

roots of English law, courts have been unwilling to accept that the precautionary principle presents a ground for judicial review.⁶

This first section of this chapter gives a brief overview of the emergence of the precautionary principle in UK policy. The second section introduces case law that cites the notion of precaution, and illustrates that there has been little judicial progress since the Court of Appeal's judgment in *Duddridge*.⁷ The final section draws conclusions about the interpretation of precaution as a rigid principle. In doing so, it refers to the relationship between precaution and scientific risk assessment. The argument is that the use of risk assessment to determine the operation of the precautionary principle necessarily places scientific inquiry at the heart of regulatory decision-making. On a broad level, the connection between law and science is However, Fisher observes an evident in the philosophy of common law. inconsistency between the polycentricity of scientific problems intrinsic to risk assessment and the linearity of legal arbitration.⁸ This provokes a tension between, on the one hand, a conceptual connection between common law and science, and, on the other hand, the judicial incompetence in dealing with highly complex and specialised scientific questions.

In my opinion, developments in the scope and application of the precautionary principle in the UK have been insignificant – relative to its evolution in international and EC law and policy. The failure by O'Riordan and Cameron to include a detailed analysis of precaution in the UK in their 2001 *Reinterpreting the Precautionary Principle* is indicative of its static existence on the domestic scene.⁹ This is certainly

RECIEL 144-151. De Sadeleer observes (at page 146) that, in Germany, judges have tended to use the notion of precaution in order to have firm control over administrative decisions. He cites a number of administrative cases in which the precautionary principle is interpreted as a procedural matter rather than a rigid principle of substantive impact (see pages 145-147).

⁶ Fisher extends her inquiry to Anglo-Commonwealth jurisdictions, where, she argues, the precautionary principle has been recognised as a ground of review. See Fisher, E. (2001) at pages 316 and 324-327.

⁷ R v. Secretary of State for Trade and Industry, ex parte Duddridge 7 (1995) Journal of Environmental Law 224.

⁸ Fisher, E. (2001) at page 317.

⁹ Despite the fact that O'Riordan and Cameron's *Interpreting the Precautionary Principle* (Earthscan Publications Ltd; London; 1994) included a chapter detailing the development of the principle in UK law, the 2001 reworking of the title omitted any such examination (O'Riordan, T. *et al* (eds) *Reinterpreting the Precautionary Principle* (Cameron May; London; 2001).

reflected by the word length of this chapter. For the sake of completeness, however, I felt that a consideration of precaution in the domestic context was necessary.

5.1 Historical analysis

There is no doubt that the Government is committed to the precautionary principle in its policy documents.¹⁰ The following statement, made by the Earl of Caithness in the House of Lords, is the earliest evidence that the Government endorsed the precautionary principle as an integral component of environmental protection:-

"Environmental policy must evolve on the basis of sound science, informed debate, foresight and a proper balance between development and conservation. We accept the precautionary principle."¹¹

The UK had already accepted the precautionary *approach* two months earlier when it became a signatory to the Declaration of the Second Conference on the North Sea in November 1987. It is interesting to note the shift in the terminology used – from the word 'approach' to the word 'principle'. Haigh recognises that this may or may not have been a deliberate move,¹² but it is interesting to highlight that the terms precautionary *approach*, precautionary *action* and precautionary *policy* appear in subsequent official documents, although the term 'precautionary principle' did not appear again until the White Paper *This Common Inheritance: Britain's Environmental Strategy* in 1990,¹³ which stated that:-

¹⁰ See, for example, DEFRA (Wilkinson, P. et al) Identification of Information Needed to Decide with Confidence on the Long Term Management of Options for Long Lived Radioactive Waste (HMSO; London; October 2002) at page 125, section 4.4.1; DEFRA, The GM Dialogue: Government Response, 9 March 2004 (HMSO; London; 2004) at pages 14-15, paragraphs 5.2 and 5.3; DEFRA, Achieving a Better Quality of Life: Review of Progress Towards Sustainable Development – Government Annual Report 2003, March 2004) (HMSO; London; 2004) at page 18, paragraphs 2.13-2.15; DEFRA, Evidence and Innovation: DEFRA's needs from the Sciences Over the Next 10 Years (HMSO; London; 2004) at page 17, at paragraph 5.7.

¹¹ per Lord Caithness, The Minister of State for the Environment, Hansard 1988 H.L. Col. 1311.

¹² Haigh, N. 'The Introduction of the Precautionary Principle into the UK', in O'Riordan, T. and Cameron, J. (eds) *Interpreting the Precautionary Principle* (Earthscan Publications Ltd; London; 1994) at page 238.

¹³ DEFRA, Cm 1200 (1990)

"[w]here there are significant risks of damage to the environment, the Government will be prepared to take precautionary action to limit the use of potentially dangerous materials or the spread of potentially dangerous pollutants, even where scientific knowledge is not conclusive, if the balance of likely costs and benefits justifies it ... The precautionary principle applies particularly where there are good grounds for judging either that action taken promptly at comparatively low cost may avoid more costly damage later, or that irreversible effects may follow if action is delayed."¹⁴

The White Paper is has been described as "one of the most authoritative interpretations provided by the British Government on the subject."¹⁵ Yet, although it demonstrates a firm policy commitment to the notion of the precaution, it lacks in practical content.¹⁶ The Department of the Environment's guidance, issued five years later, was arguably of greater practical significance, confirming the close relationship between risk assessment and the application of precaution.¹⁷ These guidelines were subsequently revised, providing an over-arching framework for the operation of precaution in relation to risk assessment.¹⁸ The opening chapter described the precautionary principle and risk assessment as complementary processes, noting that "[i]n reality, risk assessment is often employed where issues are not clear and can be used to identify effects considered serious enough to warrant precautionary action."¹⁹

The Government's Strategy for Sustainable Development²⁰ endorsed this commitment to the precautionary principle meant that it was no longer acceptable to claim that "we can't be sure that serious damage will happen, so we'll do nothing to prevent it".²¹ The Strategy also went on to note that precautionary action must be based on an 'objective assessment'²² of costs, benefit, and the degree of scientific certainty. The

¹⁴ paragraph 1.18.
¹⁵ Haigh, N. (1994) at page 238.

¹⁶ Bell, S. and McGillivray, D. Environmental Law (Blackstone Press; London; 5th edition; 2000) at page 51.

Department of the Environment, A Guide to Risk Assessment and Risk Management for Environmental Protection (HMSO; London; 1995).

¹⁸ DEFRA, Environmental Protection: Guidelines for Environmental Risk Assessment and Management (HMSO; London; 2000).

¹⁹ DEFRA, Guidelines for Environmental Risk Assessment and Management (HMSO; London; 2000) at paragraph 1.5.

²⁰ DETR, A Better Quality of Life: A Strategy for Sustainable Development in the United Kingdom (HMSO; London; 1999).

²¹ *Ibid.* at paragraph 4.2.

²² Ibid.

precautionary principle was subsequently interpreted as having a central role in the reduction of radioactive waste.²³ A consultation document explained that precautionary responses were suitable when:-

"there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may create hazards to human health, harm living resources and marine ecosystems, damage amenities or interfere with legitimate use of the sea, even when there is no conclusive evidence of a causal relationship between the inputs and effects."²⁴

The most compelling evidence of the Government's support of precaution came in its response to the Phillips Inquiry,²⁵ in which it observed that a key lesson from the BSE epidemic was the need for a more consistent approach to the precautionary principle.²⁶ As my case-study set out in the later stages of this thesis illustrates, the BSE crisis provided a classic forum upon which the operation of precaution in the face of scientific uncertainty could be tested. Yet, despite claims that the precautionary principle was employed in the legislative scheme adopted in response to concerns that BSE might transmit to humans, evidence suggests that legal provisions reflected the notion of risk prevention rather than precaution. Chapters Ten to Twelve present a detailed examination of events following the initial identification of BSE in November 1986. It is shown that the workability of the precautionary principle was dependent not only on a consensual understanding of its meaning and scope, but also on broader questions of the role of risk assessment in determining its application. For now, however, it is enough to recognise that the Phillips Inquiry is evidence that precautionary philosophy is perceived as a critical component of the pre-emption of uncertain hazards.

In its 2002 report, *The Precautionary Principle: Policy and Application*, the Interdepartmental Liaison Group on Risk Assessment (ILGRA) highlighted that,

²³ DEFRA, UK Strategy for Radioactive Discharges 2001-2020, Consultation Document (HMSO; London; June 2000).

²⁴ *Ibid.* at chapter 2, section 1, page 12.

²⁵ DEFRA, *Response to the Report on the BSE Inquiry*, Cm 5263 (HMSO; London; 2001); see also The Inquiry into BSE and Variant CJD in the United Kingdom (HMSO; London; 2000).

²⁶ DEFRA (2001) at paragraph 5.3.

although it was widely accepted that the precautionary principle should be applied in the management of hazardous activities, there was still considerable debate as to what the principle meant in UK policy. It concluded that "[t]here is an obvious need for consistency between Departments."27 In the same year, the Department for Environment, Food and Rural Affairs pledged that all its policies would reflect a precautionary approach in line with the Nice European Council Resolution on the Precautionary Principle²⁸ and the guidance issued by ILGRA.²⁹

The emergence of new 'strategic commissions' relating to specific health concerns has also resulted in the promotion of precautionary policy appraisals. The Independent Expert Group on Mobile Phones, set up in 1999 to assess possible health risks from mobile phones, base stations and transmitters, reported that the precautionary principle should be adopted until more detailed and scientifically robust information on health effects was made available.³⁰ Support for the precautionary principle has also been demonstrated by the Advisory Committee on Pesticides,³¹ and the Committee on Safety of Medicines.³² This approach to health risks has recently

"[w]hen reviewing existing approvals the ACP does not make explicit decisions that it will or will not apply the precautionary principle. Rather it aims to give due weight to all uncertainties in the risk assessment, whether they relate to risks from continuing or withdrawing approval."

²⁷ ILGRA (HMSO; London; 2002) at page 4.

²⁸ DEFRA, Foundations for our Future – DEFRA's Sustainable Development Strategy (HMSO; London: June 2002).

²⁹ *Ibid.* at page 7, section 2.9.

³⁰ IEGMP, *Mobile Phones and Health* ('The Stewart Report') (IEGMP; Oxon; 2000) http://www.iegmp.org.uk/report/index.htm, accessed June 2004, at section 6.40.

DEFRA and HSE, Advisory Committee on Pesticides, A Guide to Pesticide Regulation in the UK and the Role of the Advisory Committee on Pesticides, ACP 19 (311/2005) (HMSO; London; 2005) at page 16. The Report adopted a more ambivalent approach to precaution, stating that:-

I would like to express sincere thanks to Professor David Coggon, Chairman of the Advisory Committee on Pesticides, for his valuable comments.

³² In 2003, the Committee on Safety of Medicines (CSM) advised that Metrodin High Purity should no longer be used in the UK. Metrodin High Purity is most commonly used to stimulate the ovary in women undergoing invitrofertlilisation (IVF), or in women who have a hormonal deficiency leading to a failure to ovulate. See Department of Health Press Release issued on 10 February 2003. Professor Alasdair Breckenridge, Chairman of the CSM stated that:-

[&]quot;CSM has advised the withdrawal of Metrodin HP purely as a precautionary measure. The Committee carefully considered this issue and advised that even a theoretical risk such as that associated with Metrodin HP was unacceptable given that there are alternative treatments. It is stressed that there have been no reported cases of the transmission of CJD via urine or products derived from urine."

been endorsed by the Government in its response³³ to a report issued by the House of Commons Science and Technology Committee in March 2005 on Human Reproductive Technologies and the Law.³⁴ The Department of Health accepted that the notion of precaution had a definite role in assessing threats to health, insisting that the precautionary principle applied to threats which "may not be susceptible to demonstration and evidence in advance."³⁵

Despite the fact that the precautionary principle as set out in Article 174 EC Treaty does not have direct effect in domestic law,³⁶ anticipatory responses to risk are enshrined in a number of UK legal regimes. It follows that the precautionary principle has effect in the UK only to the extent that the Government implements it in its own policy and legislation, or EC institutions adopts a provision embodying precaution that legally binds Member States.³⁷ Maurice Kay J., for example, claims that the Waste Management Licensing Regulations 1994 are, in effect, a 'restatement' of the precautionary principle.³⁸ Similarly, precaution has been upheld in planning

³³ Department of Health, Government Response to the Report of the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005 (HMSO; London; 2005).

³⁴ Cm 6641, August 2005. The Report responds to the House of Commons Science and Technology Committee Report on 'Human Reproductive Technologies and the Law', Fifth Report of Session 2004-05, HC 7-I, March 2005.

 ³⁵ Department of Health (2005) at paragraph 6. It went on to note that "the application of a precautionary approach requires that consideration of harms to society or to patients must include the consideration of potential harms to future offspring."
 ³⁶ See, for example, R. v. Derbyshire County Council, ex parte Murray [2001] Environmental Law

 ³⁰ See, for example, R. v. Derbyshire County Council, ex parte Murray [2001] Environmental Law Reports 26, at paragraph 17.
 ³⁷ See, for example, General Product Safety Regulations 2005, which transpose Council Directive

³⁷ See, for example, General Product Safety Regulations 2005, which transpose Council Directive 2001/95/EC on general product safety. Section 10(5) (which reflects Article 8(2)(f) of the Directive) requires that "[a]n enforcement authority shall in enforcing these Regulations act in a manner proportionate to the seriousness of the risk and shall take due account of the precautionary principle." Similarly, the Notification of New Substances (Amendment) Regulations 2002, which amends the Notification of New Substance Regulations 1993 and implements paragraphs 7 and 8 of Article 1 of Directive 2001/59/EC, enshrines the precautionary principle. Section 3(b) provides that:-

[&]quot;[i]f emissions can be anticipated to occur, rigorous exposure control must be achieved by appropriate techniques, noting the need to adopt the precautionary principle in that physicochemical, toxicological or ecotoxicological properties which had not been tested shall be assumed as being hazardous."

³⁸ R. v. Derbyshire County Council, ex parte Murray [2001] Environmental Law Reports 26, at paragraph 17. See section 15(4)(ii), for example, which states that "all technical precautions will be taken to ensure that no substance in list I can reach other aquatic systems or harm other ecosystems". A precautionary approach is also evident in the Water Resources Act 1991, for example, under which the Secretary of State has power to issue regulations that take precautions against water pollution (section 92). See Bell, S. and McGillivray, D. *Environmental Law* (Oxford University Press; 6th edition; Oxford; 2005) at page 76.

policy as a means of operationalising the concept of sustainable development.³⁹ However, it is often perceived as being at odds with a general presumption in favour of development traditionally associated with English planning law.⁴⁰ The following extract, taken from the Examination in Public report on the Cambridgeshire Structure Plan, illustrates this tension:-

"It is hard to see how it [the precautionary principle] can be reconciled with the advice in PPG1 that there is a presumption in favour of development proposals which are in accordance with the development plan. We can foresee a number of difficulties in its application, and the role of planning authorities in relation to other agencies on whose advice they will presumably have to rely in whole or in part in determining planning applications and in preparing local plans. We consider that it is premature to include the precautionary principle as a policy now."⁴¹

Despite academic support for the application of precaution in UK planning,⁴² there has been relatively little debate as to the manner in which it might operate in this context.⁴³ The principle does not feature strongly in Planning Policy Guidance (PPG) Notes – other than in PPG23 Planning and Pollution Control⁴⁴ which endorses a precautionary approach to the prevention of pollution. Indeed, planning law and policy presents an interesting conceptual dilemma for the notion of precaution, requiring a trade-off between the potential benefits of development and costs of environmental degradation. Unsurprisingly, the precautionary principle does not

³⁹ See, for example, Planning Policy Guidance (PPG) Note 25: Development and Flood Risk, at paragraphs 9-14; and PPG Note 20: Coastal Planning, at paragraph 2.16.

⁴⁰ This general presumption was modified in 1991 by the Planning and Compensation Act which created a presumption in favour of development in accordance with the terms of the Development Plan. Furthermore, the presumption must be read in the light of more recent steps taken by the Government to encourage sustainable development, and its efforts to introduce a presumption against inappropriate development in Green Belts, for example (PPG Note 2: Green Belts).

⁴¹ Cambridgeshire County Council, Cambridgeshire Replacement Structure Plan: Examination in Public, Report of the Panel (Cambridgeshire County Council; Cambridge; 1995)) at 83.

⁴² Blowers, A. (ed) *Planning for a Sustainable Environment* (Earthscan; London; 1993) at page 134; Healey, P. and Shaw, T. 'Changing Meanings of 'Environment' in the British Planning System' (1994) *Transactions of the Institution of British Geographers*, NS19, pages 425-438.

⁴³ Counsell, D. 'Prudent Pessimism or Sitting on the Fence: Has the Precautionary Principle a Role in UK Development Plans?' (2002) 17(1) *Planning Practice & Research* 5-16, at page 8.

⁴⁴ Note that PPG 23 has been replaced by Planning Policy Statement (PPS) 23: Planning and Pollution Control. Paragraph 6 of PPS 23 also endorses the precautionary principle.

always sit well with those with development interests,⁴⁵ and it is perhaps for this reason that it has had a rather more ancillary role on the planning agenda than in international and EC environmental law. In a questionnaire recording stakeholder responses to the Bedfordshire County Council Structure Plan,⁴⁶ for example, a developer considered that:-

"[t]he precautionary principle has no place in planning. Development deemed to be needed must be planned for in the most sustainable way, this is the *raison d'etre* of the development plans system. It is not acceptable to sit on the fence saying 'I'm not sure about this'."⁴⁷

Nonetheless, the English Courts have helped to ensure that the precautionary principle is firmly-established in the rhetoric of planning guidelines. In response to an application for the judicial review of a local authority decision to grant planning permission for the construction of a housing site in an area at high risk of tidal flooding, the High Court upheld the principle pursuant to paragraph 8 of PPG 25, requiring risk-aversion in the face of hazards that were not 'susceptible to certainty of prediction'.⁴⁸ Furthermore, the Court of Appeal, in its consideration of the operation of precaution under PPG 8, endorsed the application of precaution before 'scientifically robust' information became available.⁴⁹

⁴⁵ Counsell, D. (2002) at page 9.

⁴⁶ Bedfordshire County Council, *Bedfordshire Structure Plan 2011: Deposit Draft* (Bedfordshire County Council; Bedford; 1995).

⁴⁷ as cited in Counsell, D. (2002) at page 9.

⁴⁸ The Queen on the Application of Thomas Bates & Son Limited v. Secretary of State for Transport, Local Government and The Regions, Maldon Borough Council [2005] JPL 343, at paragraph 21. See also, R (On the Application of Thomas Bates & Sons Ltd.) v. Secretary of State for Transport, Local Government and The Regions [2005] 2 Property Planning and Compensation Reports 11. Harrison J. upheld the notion of precaution, interpreting the guidance in PPG 25 relating to the issue of flood risk as a requirement that planning authorities apply the precautionary principle through a risk-based search sequence to avoid such risk where possible and to manage it where that is not possible (at paragraph 23).

⁴⁹ T-Mobile Ltd, Hutchinson 3G UK Ltd, Orange Personal Communications Services Ltd v. The First Secretary of State, Harrogate Borough Council [2004] EWCA Civ 1763, at paragraph 11.

5.2 Case law

Both Fisher⁵⁰ and Whitehouse⁵¹ agree that the 'true test' of the precautionary principle lies in the willingness of the courts to apply it in judicial review proceedings. In contrast with international and EC levels, there has been little case law in the UK relating to the precautionary principle since the leading case of *Duddridge*.⁵² Here, the Court of Appeal upheld the Secretary of State's decision to set a high threshold of evidence of scientific risk before precautionary action would be triggered. The applicants submitted that the mere possibility of significant harm, no matter how scientifically uncertain, could bring the precautionary principle under Article 130r EC Treaty⁵³ into operation. In his judgment, Smith J. noted that there was a clear distinction between the applicants' contention that the precautionary principle applied where there was a *possibility of increased risk* of injury and the Government's White Paper formulation that it operated in the face *significant risks of damage*.⁵⁴

Having concluded that "[t]here is, at present, no comprehensive and authoritative definition of the precautionary principles",⁵⁵ Smith J. claimed that she was left with no choice but to conclude that the Secretary of State was under no legal obligation to implement it. Interpretations of the precautionary principle as "a statement of *commonsense*"⁵⁶ lacked the sufficient precision to create compel a decision-maker to take specific action.⁵⁷ Smith J. adopted a deferential approach illustrated by EC

⁵⁰ Fisher, E. 'Is the Precautionary Principle Justiciable?' (2001) 13(3) Jnl of Environmental Law 315-334, at page 321.

⁵¹ Whitehouse, J. 'The Legal Profession: Translating Principles into Practice, in Sustainability: Principles to Practice, Proceedings' (1994) *Fenner Conference on the Environment* (Department of the Environment, Sport and Territories; Canberra; 1996) at page 59.

 $^{^{52}}$ R v. Secretary of State for Trade and Industry, ex parte Duddridge 7 (1995) JEL 224. Lee notes that ex parte Duddridge "represents the most detailed review of the application of the precautionary principle in the English courts", Lee, R. G. (Pre)cautionary Tales: Risk, Regulation and the Precautionary Principle' in Lee, R. G. and Boswall, J. (eds) Economics, Ethics and the Environment (Cavendish; London; 2002) at page 94.

⁵³ Now Article 174(2).

⁵⁴ Cm 1200 (1990) at paragraph 1.15.

⁵⁵ R v. Secretary of State for Trade and Industry, ex parte Duddridge, at page 226.

⁵⁶ Ibid. at page 281; for the interpretation of precaution as a principle of commonsense, see Leatch v. National Parks and Wildlife (1993) 81 LGERA 270.

⁵⁷ R v. Secretary of State for Trade and Industry, ex parte Duddridge at page 234.

Courts, concluding that the Secretary of State had already adopted a precautionary approach.⁵⁸

Fisher claims that this deferential approach is evidence of the perceived lack of competence on behalf of the courts to deal with matters requiring a level of expert knowledge.⁵⁹ She claims that the application of the precautionary principle "requires the application of expert knowledge to a science/policy problem that is highly polycentric."⁶⁰ On a conceptual level, the polycentricity of scientific evidence is presented as being incompatible with the more linear structure of legal arbitration. The underlying argument is that there is an inherent tension between the spheres of law and science. Fisher's basic premise is that, as a result of the nature of legal review, the law is an unsuitable vehicle through which science might be translated. As a result, either the courts do not consider the precautionary principle, or when they do, they usually defer to the anticipatory approach of the decision-maker.⁶¹

This problem of non-justiciability, however, is reflects the assumption that the application of the precautionary principle is primarily reliant on scientific prediction. The argument that the precautionary principle requires a consideration of complex scientific information is indicative of the operational relationship between precaution and risk assessment processes. More generally, this connection between law and science reflects the legitimating function of scientific knowledge.⁶² This theme is further developed in Chapter Twelve.

⁵⁸ *Ibid.* at page 226, emphasis added. See Fisher, E. (2001) at page 324. A deferential approach has also been illustrated in *R v. Chief Constable of Sussex ex parte International Trader's Ferry Ltd* [1999] 2 AC 418, see page 430, in which Lord Slynn of Hadley remarked that:-

[&]quot;[t]he courts have long made it clear that, though they will readily review the way in which decisions are reached, they will respect the margin of appreciation or discretion which a [decision-maker] has."

⁵⁹ Fisher, E. (2001) at page 321.

⁶⁰ *Ibid.* at page 322.

⁶¹ *Ibid.* at page 327. See also, Stein, P. (2000) at page 2.

⁶² For a detailed discussion, see McEldowney, J. 'The Environment, Science, and Law' (1998) 1 Current Legal Issues 109-127, particularly at pages 109-112.

Yet, in contrast with, on one level, using scientific risk assessment to determine the operation of precaution,⁶³ and on another level, the affiliation between common law and science; Fisher submits that the ability of courts to review the application of the precautionary principle is curtailed by judicial incompetence in relation to scientific problems. This creates a discord between the simultaneous dependence of precaution on scientific inquiry and the inability of judges to evaluate technical issues. Similar tensions are identified in later chapters of this thesis - particularly those dealing with the link made by social theorists between risk and modernity. In addition, the BSE case-study in Chapters Ten to Twelve illustrates interrelationships between science, precaution and risk regulation.

5.3 **Precautionary process**

Underlying the observation that there is a conflict between the review of scientific information and judicial competence is the notion that the precautionary principle is often perceived by the courts as a rigid decision algorithm.⁶⁴ Fisher suggests that the problems of definitional imprecision and reliance on scientific expertise are overcome when the precautionary principle is interpreted in terms of procedural fairness.⁶⁵ This draws attention to an important dichotomy between the precautionary principle as a fixed principle of substantive impact, and the precautionary principle as a matter of By policing the process through which precautionary decisions are process. administered, the courts are able to avoid being drawn into a debate as to the precise meaning of 'the' precautionary principle and the precision of scientific assessment, instead adjudicating the merits of the way in which decision-making is conducted.

⁶³ DEFRA, The GM Dialogue: Government Response (HMSO; London; 2004) at paragraph 5.6: "A risk-based approach to the regulation of GMOs is entirely consistent with the precautionary principle." See also, GM Science Review Panel, GM Science Review: An Open Review of the Science Relevant to GM Crops and Food Based on Interests and Concerns of the Public, First Report, July 2003, at paragraph 3.2, which presents precaution as an inherently scientific response to uncertain, ambiguous, or disputed information. ⁶⁴ Fisher, E. (2001) at page 320.

⁶⁵ Fisher, E. (2001) at page 328; see Bridgetown Greenbushes Friends of the Forest Inc v. Executive Director of the Department of Conservation and Land Management (1997) WAR 102 at page 118; Mohr v. Great Barrier Reef Marine Park Authority [1998] AATA 805 at paragraph 124; Conservation Council of South Australia v. Tuna Owners Association (No.2) [1999] SA ERDC 86 at paragraph 24.

It is interesting to consider the ability of domestic courts to review precautionary process. Galligan notes that UK jurisprudence on procedural fairness has been 'threadbare', indicating that developing the competence of UK courts is likely to be problematic.⁶⁶ Moreover, it has been observed that if the courts *do* endorse the precautionary principle as a process rather than a rigid rule, there is evidence to suggest that they might still inappropriately conceptualise 'procedural fairness' as a matter of 'fact finding'.⁶⁷ Consequently, it has been strongly argued that, should the development of the precautionary principle in this procedural context occur, it "should be within the administrative and legislative spheres of government."⁶⁸ However, Galligan points out that the concept of procedural fairness in the UK lacks any systematic and coordinated approach to its implementation, meaning that, in any particular case, the elements of procedural fairness are not always fulfilled.⁶⁹ He notes that:-

"[w]hether particular groups or interests are consulted can be a matter of chance, and the informality of the system may lead to consultation being selective and partial. The result often is that instead of being open and public, rules are made behind closed doors and in secret. Since administrators do not have to explain or justify the rules they make, we cannot always be sure that the range of opinions and the various interests are properly taken into account."⁷⁰

That said, it is arguable that the operation of the precautionary principle is beginning to display procedural attributes that mark a new approach to precautionary thinking. In recent years, and without prompting from domestic courts, the Government's precautionary policy has developed into a more robust interpretation of the principle in relation to the protection of human health and the environment. This has transpired in response to concerns about the regulation of genetically modified (GM) organisms. A statement made by the Secretary of State for Environment, Food and Rural Affairs

⁶⁶ Galligan, D. J. Due Process and Fair Procedures: A Study of Administrative Procedures (Clarendon Press; Oxford; 1996) at page 487.

⁶⁷ Chayes, A. 'The Role of the Judge in Public Law Litigation' (1996) 89 Harvard LR 1281, at page 1297; Dixon v. Australian Fisheries Management Authority [2000] AATA 442.

⁶⁸ Fisher, E. (2001) at page 333.

⁶⁹ Ibid.

⁷⁰ Ibid.

verified that the Government's approach to GM crops would be firmly based on the precautionary principle.⁷¹ It is interesting that the notion of precaution in this context is very much associated with the process of regulatory decision-making, such as public participation and transparency. Although policy documents have long made a connection between precaution and stakeholder participation, this relationship is often simply a rhetorical commitment rather than a procedural reality. In relation to the regulation of GM organisms, however, the relationship between the precautionary principle, and transparent and inclusive decision-making has been implemented in practice. The public GM debate,⁷² launched in June 2003, and overseen by an independent steering board chaired by Professor Malcolm Grant,⁷³ has been pivotal in the application of precaution through a participatory approach to risk characterisation. The Agriculture and Environment Biotechnology Commission observed that scientific research agendas are beginning to encompass broader social dimensions.⁷⁴ Levidow and Carr have also recognised that "eventually the scientists learned how to ask questions which would concern consumers".⁷⁵ By extending the question of risk perception beyond narrowly-scientific assessment, the precautionary principle can be seen to apply in relation to a broader number of threats.

The relationship between precaution and the manner in which risk is constructed is central to this thesis. The following chapters in Part Two offer a theoretical

⁷¹ Secretary of State for Environment, Food and Rural Affairs, statement on genetic modification, at paragraph 5. See also, DEFRA, *The GM Dialogue: Government Response* (HMSO; London; 2004) at paragraph 5.4. See also, DEFRA, Advisory Committee on Releases to the Environment, Annual Report 8, October 2001 (HMSO; London; 2002) at paragraph 2.4.

⁷² Called 'GM Nation?'. For further information, see <u>www.gmnation.org.uk</u>

⁷³ Chair of the Agriculture and Environment Biotechnology Commission. The steering board published its report on 24 September 2003, *GM Nation? Findings of the Public Debate*, concluding (at paragraph 51) that:-

[&]quot;Supporting the concept of precaution, although less often explicitly cited, is the memory of **previous unforeseen disasters**. The most common is BSE, followed by foot-andmouth, tobacco, Chernobyl (and nuclear power generally), DDT, SARS, and many local and individual examples, including the grey squirrel, hedgehogs in Scottish islands and the spread of Japanese knotweed in Wales. They are all used, especially BSE, to suggest that government and scientists cannot be relied on when they say that some new phenomenon is safe, and that government cannot necessarily be trusted to act in the interests of the general public rather than producers."

⁷⁴ DEFRA, Agriculture and Environment Biotechnology Commission, What Shapes the Research Agenda in Agricultural Biotechnology? (HMSO; London; 2005), at page 2.

⁷⁵ Levidow, L. and Carr, S., UK: Precautionary Commercialization? (2000) 3(3) *Journal of Risk Research* 261-270. The authors quote (at page 265) the former chairman of the Advisory Committee on Novel Foods and Processes.

explanation for the relationship between constructions of risk and scientific knowledge. As case law has demonstrated, an affiliation between science and risk assessment is central to understandings of precaution. The WTO Appellate Body, for example, has maintained that definitions of risk are to be 'based on' risk assessment procedures – and, despite claiming that the scope of risk assessment should extend beyond scientifically-informed interpretations of risk, the Court rejected findings that did not uphold the tenets of scientific discourse.⁷⁶ The relationship between science and risk assessment is also evident – although perhaps less so than in the international sphere – in the EC. The CFI in *Pfizer*, for instance, made an explicit link between risk assessment and scientific findings, claiming that constructions of risk had to be scientifically-verified.⁷⁷ And, although more recent case law in the EC is perhaps indicative of a move away from the traditional reliance of risk assessment on exclusively-scientific perceptions of the future,⁷⁸ the science-risk nexus continues to dominate hazard decision-making.⁷⁹

This chapter has presented precaution and risk assessment from a distinctly UK perspective. Despite the fact that the evolution of the precautionary principle in domestic law and policy has been far less contentious than its development in international and EC spheres, broad questions about the relationship between precaution and scientific risk assessment have still emerged. Fisher has led the debate in this area, identifying a tension between the complexity of scientific inquiry and the linear nature of legal arbitration. She concludes that this problem of judicial incompetence can be overcome if precaution is construed as a procedural obligation as opposed to a decision-making algorithm requiring courts to judge the merits of scientific evidence. This chapter has suggested that the application of the precautionary principle in relation to GM organisms might be interpreted as an

⁷⁶ EC-Measures Concerning Meat and Meat Products (Hormones) WTO Appellate Body Report: WT/DS26/AB/R and WT/DS48/AB/R, 16 January 1998, at paragraphs 192-198.

⁷⁷ Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union.* 11 September 2002. European Court Reports 2002 page 00000, at paragraphs 143-145.

⁷⁸ See Case C-41/02, Commission of the European Communities v. Kingdom of the Netherlands at paragraph 54.

⁷⁹ See, for example, guidance issued by the EC Commission in its Green Paper on *The General Principles of Food Law in the EU*, COM(97) 176, 30 April 1997.

indication of its association with procedural fairness – specifically through increased stakeholder participation and transparency in policy-making.⁸⁰

The dependency of risk assessment on scientific method in prediction is best understood with reference to the theoretical backdrop to precaution. The following chapter begins by marking the distinction between calculable risk and incalculable uncertainty. It shows that, in accordance with conventional models of scientific assessment, risk is seen as a quantifiable entity; whereas uncertainty is perceived to be unquantifiable. This calculable/incalculable dichotomy is crucial because the precautionary principle is deemed to operate in the face of incalculable uncertainty, but not calculable risk. The chapter presents the concept of risk in the light of its long-established connection to scientific quantification. By virtue of its scientific underpinnings, risk calculations are portrayed as *objective*, *rational*, and *certain* units. This has major implications for the application of precaution – not least because it introduces a conceptual conflict between the propensity for scientific assessment to frame the future in *certain* terms and the typically-precautionary interpretation that impending hazards can be scientifically uncertain. The following part of this thesis explores broader issues of science, risk and precaution using economic theory, scientific discourse and social science insights as a conduit. A BSE case-study in the last part of this thesis is illustrative of these themes, and provides evidence to suggest that there is an inherent conflict between the regulation of risk and the aspirations of precaution.

⁸⁰ A Memorandum submitted by GeneWatch UK has noted that "[t]his was a novel and welcome step that brought the possibility of a new form of public participation in decision making." See House of Commons Environment, Food and Rural Affairs Committee, *Conduct of the GM Debate*, Eighteenth Report of Session 2002-03, HC 1220, 20 November 2003 (HMSO; London; 2003) at page 26, paragraph 4.

<u>Part Two</u>

<u>The precautionary principle and its relationship with 'risk'</u> <u>and 'scientific certainty'</u>

"Society's growing commitment to the precautionary principle is essentially a response to a growing tension between two aspects of science: its growing innovative powers [are] increasingly outrunning its capacity to anticipate the consequences."⁸¹

⁸¹ Harramoës, P. et al, 'Twelve Late Lessons' in Harramoës, P. et al, The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings at page 209.

Chapter Six

Theoretical backdrop to the precautionary principle

6.0 Introduction

As Part One of this thesis has illustrated, the relationship between risk assessment, and thus scientific interpretations of 'risk', and the precautionary principle is a contentious issue that remains unresolved. Judgments passed by international and European courts have tended to lend support for the argument that the application of the precautionary principle is to be determined by scientific risk assessment that assigns definite quantities to impending hazards. The WTO Appellate Body, for example, has maintained that the implementation of precaution under the SPS Agreement must follow a strict and narrowly-scientific calculation of the magnitude and scale of threats to human health. This approach has subsequently been mirrored by the CFI which held that the precaution principle can only apply if a potential hazard has been scientifically verified. On this basis, the affiliation of precaution to the scientific measurements of future threats is clear. Furthermore, they serve as evidence that the operation of precaution is reliant on an absolute distinction between 'risk' and 'uncertainty'.

More recent judicial endeavours in the European context have raised questions about the dependence of precaution on the outcome of risk assessment procedures. Whilst they are not explicit in their criticism, they do serve to highlight that the practice of using risk assessment as the sole means of ascertaining the application of a precautionary response is an unsatisfactory approach to future hazards. The problem with relying on scientific risk models is not only that their assessment of the future is based on observations of a past which might bear little or no relation to potential occurrences, but also that their predictions are interpreted normatively. Numerical expressions of risk are interpreted as prescribing the appropriate course of action in response to an impending hazard. An outcome of a 2% risk of flooding, for example, is routinely translated as a very low risk to which a precautionary response is considered to be unsuitable.¹ The problem here of course is that a figure of 2% is incapable of conveying the context within which the risk assessment was conducted which might include incomplete, indeterminate, or disputed knowledge about the hazard in question.² Wynne has pioneered thinking in this field, and has demonstrated on numerous occasions the failure of scientific assessment to develop a rhetoric to express inadequate knowledge of the future. His work illustrates that the utility of risk quantification is limited by factors that do not lend themselves to numerical articulation. This has been pivotal in exposing linear definitions of risk to the charge that abstract quantification is rarely emulated in practice, although its impact on the operation of the precautionary principle remains largely unexplored.

Part Two of this thesis develops this argument that statistical predictions deriving from risk assessment processes might represent more than a simple calculation of the likely magnitude and frequency of an event. It provides a theoretical backdrop to the precautionary principle in an attempt to better understand the practical implications of using scientific risk assessment to determine its application. It begins by emphasising the relationship between the precautionary principle and risk assessment, before putting forward the argument that the results of risk assessment are normativelyinterpreted. This normative interpretation is fuelled by claims that, given that scientific observation is essentially an objective exercise, risk estimates convey a single outcome in response to which a specific course of action is required.

Stirling also notes that:-

¹ The focus here is 'false negative errors' or Type II errors. For a detailed discussion of Type II errors and the operation of precaution, see Underwood, A. J. and Chapman, M. G. 'Power, Precaution, Type II Error and Sampling Design in Assessment of Environmental Impacts' (2003) 296(1) Journal of Experimental Marine Biology and Ecology 49-70, at page 59.

² Domingo Jiménez Beltrán argues that misplaced 'certainty' about the absence of harm has played a key role in delaying precautionary responses to hazards, stating that:-

[&]quot;there is clearly nothing scientific about the pretence of knowledge. Such 'certainty' does little to reduce ignorance, which requires more scientific research and long-term monitoring in order to identify the unintended impacts of human activities."

[&]quot;The curious thing is, that these and other sources of intractable uncertainty and ignorance are routinely treated in the regulatory appraisal of technology by using the probabilistic techniques of risk assessment."

See Stirling, A. ESRC Global Environmental Change Programme on Science and Precaution in the Management of Technological Risk, Final Report, May 1999, Section 5, at <u>http://www.sussex.ac.uk/Units/gec/gecko/r9e-prc-.htm accessed June 2004</u>. See also Harremoës, P. *et al, The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings* (Earthscan; London; 2002) Preface, at page xiv.

This thesis goes on to illustrate that there is a fundamental problem with this absolutist application of risk assessment – which is further demonstrated in Part Three using a case-study of the BSE epidemic. The first is that the practice of taking risk quantities at face value is flawed because it overlooks the fact that risk is a product of social construction. From this perspective, risk calculations can be described as embodiments of not only magnitude and frequency, but also of factors such as the distribution of risk and benefits, voluntarism and consent, degree of familiarity, visibility, and control.³

Directly relating to the notion of subjective construction is that risk estimates – in their conventional mathematical format – are incapable of communicating deficiencies in knowledge, such as inconsistency, indeterminacy, and disputed accuracy. In the same way that the numerical assessment of risk should be construed as a medium through which subjectivity can manifest, it should also be borne in mind that risk statistics are also unable to communicate the fact that their manufacture was based on imperfect knowledge. If it is accepted that the quantification of risk is inherently- but unrealistically- dependent on there being a complete and objective knowledge base, then it is feasible to argue that a precautionary response might be appropriate in the face of risk that is presented as being certain and known.

Constructivist theories, propounded by authors such as Douglas and Wildavsky, have been useful in presenting an interpretation of risk to counter the argument that risk is an objectively quantifiable entity. They serve to highlight that perceptions of future hazards are essentially the product of individual bias and contextual factors that mould our assessment of the unknown. From this sociologically-driven perspective, the concept of risk can be described as a subjective construction whose existence is incapable of independent measurement. In this respect, numerical expressions of risk

³ See the works of authors, such as Slovic, P. 'Beyond Numbers: A Broader Perspective on Risk Perception and Risk Communication', in Mayo, D. G. and Hollander, R. (eds) *Acceptable Evidence: Science and Values in Risk Management* (Oxford University Press; Oxford; 1991); Wynne, B. 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111-127; Wynne, B. 'Creating Public Alienation: Expert Cultures of Risk and Ethics of GMOs' (2001) 10 *Science as Culture* 303-305; and Renn, O. 'Three Decades of Risk Research: Accomplishments and New Challenges' (1998) 1 *Journal of Risk Research* 44-71.

are a manifestation of more than objective assessments of impending hazards, and thus should not be taken as conclusive and factual accounts of the future.

The danger with a solely-constructivist approach to risk, however, is that suggests that risk assessment in the traditional sense is always a redundant procedure. This position is neither accurate, nor useful in the absence of any alternative process of measurement. Beck's thesis proposes a model that strikes a balance between objectivist and constructivist stances. He argues that there is a clear distinction between industrial and post-industrial society based on the extent to which risk assessment is able to function. Accordingly, industrial society presents hazards whose occurrence and impact can be accurately predicted using risk assessment, whereas post-industrial risk society produces threats that defy scientific quantification. It is in his risk society thesis that he draws on the argument that although risk has been accurately measured in the past, its post-industrial characteristics provide evidence that it is a social relationship rather than simply a physical danger.

Building on Beck's account of the distinction between industrial society, in which insurance-based calculations establish causal relations and liability, and contemporary risk societies, in which hazards defy models of regulatory and attribution, the precautionary principle can be seen as a response to the threats posed by new and uncontrollable hazards. Essentially, the underlying philosophy of the precautionary principle is that, given that "[n]ot everything is a matter of economics",⁴ anticipatory action is desirable in the face of unquantifiable threats. From this perspective, scientific measurement and precaution are often presented as alternative approaches to risk.

However, in spite of the fact that his thesis is founded on the notion that scientific projection in the assessment of risk in post-industrial society is limited, Beck rejects the utility of anticipatory responses to potential hazards. He argues that, because of our inability to know the impact and occurrence of future hazards, anticipatory

⁴ Ewald, F. "The Return of Descartes' Malicious Demon: An Outline of a Philosophy of Precaution", in Baker, T, and Simon, J. (eds) *Embracing Risk: The Changing Culture of Insurance and Responsibility* (University of Chicago Press; Chicago; 2002) 273-301, at page 285.

conduct, and with that precaution, are rendered impotent. This leads to what I call the 'paradox of precaution'. Beck's criticism of anticipatory action is in direct conflict with the principal reason for the emergence of precautionary conduct – that is, as a response to the limitations of scientific quantification as a means of defining the future.

Whereas industrial society is characterised by a 'paradigm of responsibility' based on principles of fault, liability and insurance, risk society presents hazards whose origin cannot be traced, and whose occurrence and magnitude are neither measurable nor assessable – thus making it impossible to attach responsibility. Neither doubt nor uncertainty provide a rational basis upon which to establish responsibility.⁵ The argument is that:-

"one can hardly see how, under current law of responsibility, one could attribute to anyone an injury of unclear origin, except by employing new systems of causal analysis, vague logic, and other systems of probably causality, or by introducing a new law of proof, or by fixing responsibilities of principle to necessarily arbitrary foundations."⁶

From this perspective, the precautionary principle might be seen as an attempt to reformulate the concept of responsibility by demanding that decision-makers have regard for potential, but unknown, consequences of their conduct. The notion of precaution is presented in the light of Hans Jonas' theory of the imperative of responsibility. On the basis of Jonas' thesis, the ability of the precautionary principle to establish responsibility is subject to the extent to which its construction of potential hazards is explicit in its recognition of the limits of scientific inquiry. Yet, despite the fact that decision-makers regularly cite the precautionary principle as a motive for anticipatory conduct in the face of the unknown, and its application is interpreted as a rebuttal of scientific measurement, the operation of precaution is still dependent on the scientific assessment of potential hazards.

⁵ Ewald, F. (2002) at page 276.

⁶ Ibid. at page 287.

Although the affiliation between the precautionary principle and risk assessment, and the 'science versus precaution' debate, are often presented as merely a rhetorical inconsistency of little practical significance, they have, in my opinion, three fundamental implications. First, the application of precaution is limited to hazards that are considered by scientific measurement to be uncertain. The notion of uncertainty in risk assessment procedures, however, is rather more restricted than broader, socially-informed interpretations. Whereas scientific assessment is based on a deeply-rooted presumption that the distinction between risk and uncertainty can be strictly maintained through quantification, in reality, the boundary between risk and uncertainty is far less clear.

The second implication, which is essentially a restatement of the first, is that a precautionary response might be suitable despite risk assessment calculations that a hazard presents a statistically-certain risk. A finding that a threat to human health or the environment can be expressed with numerical precision should not automatically rule out the operation of precaution. This is because a specific risk quantity cannot convey knowledge deficiencies to which a precautionary response might be appropriate.

The third implication is that, as a result of its narrow reliance on scientific risk assessment, the precautionary principle, in practice, displays traits that are more closely associated with the notion of risk prevention than precaution. This consequence is made evident in Part Three of this thesis which illustrates that, despite claims of its precautionary-nature, legislation adopted as a means of controlling the threat of BSE was aimed at a specific and scientifically-determined risk. A detailed case-study of the BSE crisis reveals that the dependence of precautionary conduct on the outcome of risk assessment is reflective of the intricate relationships between institutional and scientific constructions of risk, and the legitimating function of scientific certainty in the regulation of hazards.

To begin with, Chapter Six introduces the theoretical backdrop to the precautionary principle. It focuses on the traditional distinction made between risk and uncertainty, and illustrates that despite being presented as specific quantities, risk estimates are not necessarily based on objective and complete information about the future. The aim of this chapter is to demonstrate that the normative interpretation of risk calculations overlooks the fact that risk is essentially a socially-constructed phenomenon. Normative interpretations of risk work on the assumption that quantified forecasts reflect objective accounts of the future. As Chapter Seven illustrates, this position is problematic because precise expressions of risk can represent subjective and uncertain perceptions. Chapters Eight and Nine develop the argument that risk is more than a problem of measurement, introducing risk in the context of the theory of modernity. The overriding argument is that the process of determining the application of the precautionary principle should involve a consideration of factors beyond those conveyed by quantification.

6.1 Risk assessment and the precautionary principle

The dependence of the precautionary principle on scientific risk assessment has long been recognised. As preceding chapters have illustrated, judicial interpretations of precaution provide evidence that the operation of precaution is based on there being a clear distinction between 'risk' and 'uncertainty' which is established using scientific risk assessment. The centrality of scientific assessment in determining the operation of precaution is widely acknowledged. In a speech made to the American Branch of the International Law Association, for example, the EU Minister for Agriculture, Fisheries, Food Safety and Consumer Affairs declared that "[t]he implementation of an approach based on the precautionary principle should start with a scientific evaluation."⁷

The question is, what are the implications of the heavy dependence of precaution on the outcome of risk assessment procedures? In order to provide a thorough answer to this, it is necessary to consider the nature of risk assessment, and more broadly, the characteristics of scientific inquiry. It is by virtue of the objectivity and rationality of

⁷ A speech delivered by Tony Van Der Haegen, in the 'EU View of Precautionary Principle in Food Safety', New York Oct 23-25 2003, <u>http://www.eurunion.org/News/speeches/2003/031023tvdh.htm</u>, accessed May 2004. See also Weiss, C. 'Scientific Uncertainty and Science-Based Precaution' (2003) 3 *International Environmental Agreements: Politics, Law and Economics* 137-166, at page 159; and at page 161 where the author argues that "a scientific outlook should support precaution, and precaution should be based on science. 'Science-based precaution' should be shorthand for proper risk management."

risk estimates that the outcome of risk assessment can be normatively interpreted. The risk assessment process is deemed to maintain a clear distinction between risk and uncertainty, and it is perceived to produce authoritative and legitimate forecasts of the future. This innate authority is born of the underlying theory that the formal scientific discourse assures objective and rational expressions of the past, the present, and the future. The following account explores the historical analyses of the argument that the concept of risk upholds the scientific ideal of objectivity. It illustrates the way in which risk calculation has come to be associated with impartiality and precision, and it makes reference to the core assumption that scientific inquiry operates on the basis that there is a clear distinction between facts and values.

6.2 Risk: what's in a name?

"That which we call a rose, By any other name would smell as sweet."⁸

In the words of Rosa, "[r]isk has a very long past, but very short history".⁹ Notwithstanding the fact that the concept of risk has only come to dominate the social debate in the modern era,¹⁰ the concept of risk is certainly not new.¹¹ This is particularly evident in relation to *environmental* risk. It has always existed. As noted by Jaeger *et al*:-

"Far from a transient annoyance, risk is constitutive of the human condition, as it has been from the beginning of human existence. While we worry about the risk of a nuclear disaster, our ancestors worried about the risk of being devoured by other species. We worry about the risk of

⁸ Shakespeare, W. Romeo and Juliet, Act Two; Scene Two.

⁹ Rosa, E. A. 'Metatheoretical Foundations for Post-Normal Risk' (1998) 1(1) Journal of Risk Research 15-44, at page 15.

¹⁰ Beck, U. *Ecological Politics in an Age of Risk* (Polity Press; Cambridge; 1995) at page 2; see also Rosa, E. A. and Wong, S. K. 'Weaving the Social Fabric of Risk Perceptions: The Cultural Context', paper presented at the *Annual Meeting of the American Sociological Association* (Pittsburgh; PA; 1992).

¹¹ Knight, F. H. Risk, Uncertainty and Profit (Houghton Mifflin Company; Boston; 1921) at page 199.

global warming, while they worried about the risk of finding shelter to protect themselves from the Arctic cold."¹²

It is generally accepted that the origin of the word 'risk' is unknown,¹³ although a number of authors claim to have traced it. Bon β , for example, contends that the word *risk* has Arabic roots.¹⁴ Johnson and Covello, on the other hand, argue that it is a derivative of Greek and Latin expressions.¹⁵

Whichever stance is correct, it is thought that the use of risk-related jargon first appeared in Europe during the fourteenth century in a collection of Italian documents.¹⁶ Ewald notes that the Italian word *risque*, and later *risco*, were used in relation to maritime activities,¹⁷ roughly translating to 'that which rips' from which the words 'reef' and 'rock' are derived.¹⁸ On a similar note, Johnson and Covello associate 'risk' with the Vulgar Latin *resecum*, meaning 'danger', 'rock' or 'risk at sea', and the Greek *rhiza*, meaning 'cliff'.¹⁹ Giddens, on the other hand, argues that the word risk seems to have entered the English language via Spanish or Portuguese in the sixteenth and seventeenth centuries. He does, however, agree that the term was first used "by Western explorers as they set off on their voyages across the world."²⁰

Given its historical credentials, it is interesting to observe a relatively new obsession with the concept of environmental risk. Despite the age-old awareness of risk, it has only recently been thrust to the forefront of the environmental agenda as the most perturbing plight of modern society. Without doubt, contemporary culture is bedevilled by fear for ontological security and the unknown. Risk is embedded in the social fabric of the post-industrial age. It is an intrinsic part of modernity. Perhaps

¹² Jaeger, C. C. et al, Risk, Uncertainty, and Rational Action (Earthscan; London; 2001) at page 14, section 1.1.1.

¹³ Strydom, P. Risk, Environment and Society: Ongoing Debates, Current Issues and Future Prospects (Open University Press; Maidenhead; 2002).

¹⁴ Bonβ, W. (1991) at page 263.

¹⁵ Johnson, B. B. and Covello, V. T. The Social and Cultural Construction of Risk (Reidel; Dordrecht; 1987) at page i.

¹⁶ Bonβ, W. (1991) at page 263.

¹⁷ Ewald, F. 'Insurance and Risks' in Burchell, G. *et al* (eds) *The Foucault Effect: Studies in Governmentality* (Harvester Wheatsheaf; London; 1991) at pages 198-9.

¹⁸ Strydom, P. (2002) at page 75.

¹⁹ Johnson, B. B. and Covello, V. T. (1987) at page i.

²⁰ Giddens, A. 'Risk', Reith Lecture Series, 1999, Hong Kong <u>http://news.bbc.co.uk/hi/english/static/events/reith_99/week2/week2.htm</u>, accessed October 2003.

most significantly, it has become part of everyday life. News of chemical spills, food contamination, global climate change, genetic modification, the transmission of Bovine Spongiform Encephalopathy to humans, the resurgence foot and mouth disease, toxic Scottish salmon, the identification of bird flu, and the measles, mumps and rubella (MMR) vaccination dispute have become unavoidable – unsurprisingly, provoking growing paranoia over our vulnerability.

For most theorists, this new fixation is seen as being the result of a social transition to a *new* order.²¹ The onset of the new social order is associated with the demise of the industrial phase and the evolution of a new modernity, the spirit of which is marked by a preoccupation with risk. Underlying the elevation of the status of the risk discourse is the argument that the modern condition challenges the expectation of continuing progress, shifting attention to the darker sides of modernization.²² Growing realisation that scientific and technological progress can be as problematic as it is beneficial has drawn attention to the capacity of the modern condition to create as many risks as it dispels. Heightened awareness of the detrimental effects of industrial advancement firmly establishes the centrality of risk to contemporary society. The emergence of the precautionary principle has undoubtedly coincided with the onset of the new risk order. An account of the precautionary principle without reference to the risk discourse is therefore incomplete.

6.3 Risk – positivist hubris and rationality

Despite the fact that 'risk' has become a fully-fledged discipline, there is still remarkably little consensus as to its definition. At one end of the spectrum, there is an intentional avoidance of getting caught up in the definitional debate,²³ whilst at the other, risk is considered a definable entity in an objective, observable sense, and is expressed as a compound of the probability of an event multiplied by the severity of

²¹ Jaeger, C. C. et al (2001) at page 15.

²² Beck, U. (1995) at page 2.

²³ Douglas, M. and Wildavsky, A. B. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers (University of California Press; Berkeley; 1982).

its consequences.²⁴ Luhmann claims that it is "generally agreed that not too much attention needs to be paid to questions of definition, for definitions serve only to delimit, not adequately to describe (let alone explain) the object under investigation."²⁵ That said, it is useful to gain an understanding of the circumstances to which the term 'risk' is applied, if only to appreciate the conceptual distinction between risk and uncertainty.

The lacking consensus is probably best explained as a product of differences in underlying theoretical context. The natural sciences tend to claim that all eventualities can be expressed using numbers. Early economic and insurance theories, for example, portray risk in as a rational and exact measure. The social sciences, on the other hand, maintain that there is no definition of risk that could meet the requirements of natural science. Psychological and cultural theory stances assert that, in reality, people do not calculate risk with the rationality and certitude demanded by conventional decision theory.

Interestingly, despite the attack made by the social sciences on the quantification of risk, the process of risk assessment continues to express risk as the outcome of objective and rational measurement. Wynne observes that "[t]he deterministic commitment can ... be seen to reflect the instrumentalist epistemology of modern scientific culture overall".²⁶ He goes on to note that authoritative representations of scientific knowledge deletes complexity in decision-making, which "effectively denies lack of predictive control, and thus also responsibility for it."²⁷

In the face of an increasingly uncertain future, the calculation of risk is perceived as providing a secure basis for decision-making. The attaching of fixed numerical values to future events is seen as a move to extend control over the unknown and counteract the problem of human vulnerability. The ability to quantify and control

 ²⁴ Kates, R. W. and Kasperson, J. X. 'Comparative Risk Analysis of Technological Hazards (A Review)' (1983) 50 *Proceedings of the National Academy of Sciences* 7027-7038.
 ²⁵ Luhmann, N. (1993) at page 7.

 ²⁶ Wynne, B. 'Reflexing Complexity: Post-genomic Knowledge and Reductionist Returns in Public Science' (2005) 22(5) *Theory, Culture & Society* 67-94, at page 77.
 ²⁷ Ibid strates 70

²⁷ *Ibid.* at page 70.

uncertainty creates an impression of security, and this approach continues to dominate the scientific analysis of impending hazards.²⁸

• <u>6.3.1 The economics of risk</u>

Arguably, modern day notions of risk are founded in economic theory, emerging in relation to banking and insurance as a calculation of the probable consequences of investment decisions for borrowers, lenders, and insurers.²⁹ Instrumental in its statistical treatment was mathematician Frank Knight, whose economic theory sought to explain entrepreneurial profit by modelling the absorption of uncertainty.³⁰ In dealing with measures of incertitude, Knight argued that, according to probability theory, uncertainty and risk are distinct categories.³¹ Accordingly, :-

"[t]he practical difference between the two categories, risk and uncertainty, is that in the former the distribution of the outcome in a group of instances is known (either through calculation a priori or from statistics of past experience), while in the case of uncertainty, this is not true, the reason being in general that it is impossible to form a group of instances because the situation dealt with is in a high degree unique."³²

The basic premise is that risk is quantifiable, whereas uncertainty is *un*quantifiable.³³ This ability to calculate risk leads Bernstein to conclude that risk is, in effect, not an uncertainty at all.³⁴ Since quantification expresses risk with exactitude, it can be described as being certain. The presumption that risk can be reduced to a single numerical value with certainty conceptualises risk as an objective expression. It

²⁸ Luhmann, N. (1993) at page 13.

²⁹ Giddens, A. (1999).

³⁰ Knight, F. H.(1921).

³¹ See Knight, F. H. (1921); see also Keynes, J. A Treatise on Probability (Macmillan; London; 1921); Keykhah, M. 'The Shape of Uncertainty: Implications for Decision Making' (2002) Oxford Geography Working Paper Series WPG 02-03 at page 3.

³² Knight, F. H. (1921) at page 233.

³³ See, for example, Willett, A. H. 'The Economic Theory of Risk and Insurance' (2002) Columbia University Studies in Political Science, Vol. XIV, No. 2; Hawley, F. B. 'Enterprise and Profit' (1900) Quarterly Journal of Economics Vol XV 75-105, at page 88; and Hawley, F. B. 'The Risk Theory of Profit' (1893) Quarterly Journal of Economics Vol VII 459-479, at page 468.

³⁴ Bernstein, P. L. Against the Gods: The Remarkable Story of Risk (John Wiley & Sons; New York; 1996); Pritchard, P. Environmental Risk Management (Earthscan; London; 2000) at page 72.

assumes a mirror relationship between calculation and reality. As such, quantification is a means of conveying scientific truth.

On the ground that the risk calculus predicts the future with objective certainty, the concept of risk finds itself at the heart of insurance theory. Risk is, accordingly, "a neologism of insurance."³⁵ Say's Dictionary of Political Economy claims that "the *whole* theory of insurance rests on the fundamental notion of risk."³⁶ Classic insurance theory forms the backdrop against which the 'governmentality' approach to risk has developed. The relationship between the concept of risk and government was established by Foucault,³⁷ and developed by the likes of Ewald,³⁸ Castel,³⁹ and Dean.⁴⁰ From this perspective, risk is seen as a function of governmental rationality,⁴¹ constructed through knowledge, practices and techniques, and enabling the government to regulate, control, and shape human behaviour.⁴² Accordingly, a shift from traditional society to insurance society is marked by constructing the concept of risk in a quantifiable format.⁴³ Risk, according to Dean, is:-

"a way ... of ordering reality, of rendering it into a calculable form. It is a way of representing events so they might be made governable in particular ways, with particular techniques, and for particular goals. It is a component of diverse forms of calculative rationality for governing the conduct of individuals, collectives and populations. It is thus not possible to speak of incalculable risks..."⁴⁴

Risk, therefore, is a behavioural science. In order to be able to create the sense of security so fundamental to the notion of the provident state, risk is deemed to be a

³⁵ Ewald, F. (1991) at page 198.

³⁶ Say, L. Nouveau Dictionnaire d'Economie Politique, as cited in Burchell, G. et al (1991) at page 199.

³⁷ Burchell, G. *et al* (1991).

³⁸ Ewald, F. (1991).

³⁹ Castel, R. 'From Dangerousness to Risk' in Burchell, G. et al (1991) pages 281-298.

⁴⁰ Dean, M. Governmentality: Power and Rule in Modern Society (Sage; London; 1999).

⁴¹ *Ibid*. at page 176.

⁴² Lupton, D. (ed) Risk and Sociocultural Theory: New Direction and Perspectives (Cambridge University Press; Cambridge; 1999) at page 4.

⁴³ Ewald, F. *L'Etat Providence* (Bernard Grasset; Paris; 1986) at page 16; Giddens, A. 'Risk and Responsibility' (1999) 62 Modern Law Review 1, at page 9.

⁴⁴ Dean, M. 'Risk, Calculable and Incalculable', in Lupton, D. (1999) chapter 6. at page 131.

calculable entity.⁴⁵ The risk calculus reconstructs reality into an intelligible format allowing government intervention. Beck explains that "[r]isk calculations and private and state insurance policies are social answers to the challenge of the insecurities created by modernity in every area of life."⁴⁶ In order to deal with uncertainty, society requires an effective system for making uncertainty less threatening. Calculability is a response to the threat posed by risk to ontological security.

• <u>6.3.2 Risk and rationality</u>

Underpinning the notion of quantifiable risk is the concept of rationality.⁴⁷ Rationality signifies the provision of a commonly accepted method for dealing with uncertainty. This role, in contemporary Western societies at least, is performed by the scientific community. Although uncertainty presents an obstacle to collective decision making, science provides a socially-accepted system through which such obstacles can be overcome. To some extent, the relationship between scientific calculation and rationality can be observed in Weber's traditional sociological theory⁴⁸ – which was, arguably, based on the Kantian notion that "mathematics presents the most splendid example of the successful extension of pure reason, without the help of experience."⁴⁹ Weber's account of modern capitalism unites science and calculability with ideas of rationality and objectivity.⁵⁰ Quantitative reckoning was, accordingly, the defining feature of rational commerce, and thus calculability was given central significance in the theory of modern capitalism. Accordingly, calculability generates a state of rationality:-

"From a purely technical point of view, money is the most 'perfect' means of economic calculation. That is, it is formally the most rational means of

⁴⁵ Ewald, F. (1991) at page 201.

⁴⁶ Beck, U. (1995) at page 107.

⁴⁷ Jaeger, C. C. *et al* (2001) at page 20.

⁴⁸ Weber, M. 'Science as a Vocation', in Gerth, H. H. and Wright Mills, C. (eds) *From Max Weber: Essays in Sociology* (Routledge; London; 1958) pages 77-128, at pages 139 and 155; Weber, M. "'Objectivity" in Social Science and Social Policy' in Shils, E. A. and Finch, H. A. (eds) *The Methology of Social Sciences: Max Weber* (The Free Press; New York; 1969) pages 50-112; Weber, M. *Economy and Society* (University of California Press; Berkeley; 1978) part One, chapter two.

⁴⁹ Kant, I. (translated by Smith, N. K.) Critique of Pure Reason (Macmillan; London; 1933) at page 576.

⁵⁰ Weber, M. (1978), with particular reference to sections 1-14, 22, 25, 30, 31 and 41.

orienting economic activity. Calculability in terms of money is thus the specific means of rational economic provision."⁵¹

Quantitative calculation is equated with rationality because it is an exact and unambiguous means of expression. For Weber, the term 'rational' indicates evaluative neutrality.⁵² Following on from this, a distinction is made between the subjective and objective condition. Weber considers rationality to be an embodiment of *objectified* quantitative calculation⁵³ that excludes subjective elements of perception. Whereas objectivity is synonymous with realism, subjectivity is associated with ideas and beliefs that exist only in the mind.

6.4 Risk: social construction or social reality?

"The scientific man has above all things to strive at self-elimination in his judgments, to provide an argument which is as true for each individual mind as for his own."⁵⁴

The extricable link made between the concepts of calculability, rationality and objectivity uncovers a broader argument, also evident in Weber's theory of modern capitalism – that empirical science is both rational and objective. The scientific claim to legitimacy derives from the suppression of subjectivity in favour of exactitude and impartiality. Quantification is the primary means by which science is able to screen out individual biases and prejudices, thereby achieving objectivity. According to Porter, strict quantification is the most credible way of rendering nature and society objective.⁵⁵

⁵¹ *Ibid.* at page 86.

⁵² Brubaker, R. The Limits of Rationality: An Essay on the Social and Moral Thought of Max Weber (Routledge; London; 1984) at page 11.

⁵³ Ibid.

⁵⁴ Porter, T. M. Trust in Numbers: The Pursuit of Objectivity in Science and Public Life (Princeton University Press; Princeton, New Jersey; 1996) at page 75.

⁵⁵ Ibid. at page 74
The ideal of objectivity is conflated with the notions of impersonality and truth. In other words, objective quantification allows us to know things as they really are,⁵⁶ without reference to divergent individual *perceptions* of the truth. In this sense, objectivity is the hallmark of certainty. A decision made on the basis of quantitative calculation reduces reality into a simple numerical expression, making it seemingly fair and value-free. The concept of scientific objectivity provides an answer to the social demand for impartiality and certitude. As Porter puts it, quantification "is a way of making decisions without seeming to decide … [lending] authority to officials who have very little of their own."⁵⁷

Essentially, a claim to scientific objectivity assumes the use of non-arbitrary and nonsubjective method. It is rooted in positivist or realist theories of scientific knowledge which contend that objectivity is necessarily derived from the logical relationship between hypotheses and the extent to which they are directly observed. Thus, scientific *observation* provides the foundation for claims to scientific objectivity.⁵⁸ Implicit in the notion of the scientific observation, or scientific *empiricism*, is the idea that, since objective observation is possible, an objective *expression* of observation can also be attained. Objectivity, therefore, extends to scientific measurement, manifesting itself in the quantification of observed results.⁵⁹ Objective quantification leaves no room for conflicting interpretations, and can thus be described as promoting scientific certainty.

Claims of the objectivity and certainty of scientific knowledge find their roots in the works of Galileo⁶⁰ and Bacon.⁶¹ The Galilean argument is primarily a metaphysical one, claiming that the facts of nature are explicable in terms of underlying structures, processes and laws. This underlying order can only be expressed in quantifiable units. Values, as opposed to facts, are not generated by the underlying order but

⁵⁶ On the meanings of objectivity, see Daston, L. and Galison, P. 'Image of Objectivity' (1992) 40 Representations 81-128; and Daston, L. 'Objectivity and the Escape from Perspective' (1992) 22 Social Studies of Science 597-618.

⁵⁷ Porter, T. M. (1996) at page 8.

⁵⁸ Brown, H. I. Observation and Objectivity (Oxford University Press; Oxford; 1987) at page 190.

⁵⁹ Rowe, W. D. An Anatomy of Risk (John Wiley & Sons; New York; 1977) at pages 38-39.

⁶⁰ Galilei, G. The Assayer (1623), excerpts in Drake, S. Discoveries and Opinions of Galileo (Doubleday; New Jersey; 1957).

⁶¹ Bacon, F. (Anderson, F. H. (ed)) The New Organon and Related Writings (Columbia University Press; New York; 1960).

rather are the product of man assigning worth to objects as a result of experience, practice or influence of social organisation.⁶² The underlying order is a realm of pure fact without any connection to value.⁶³ Since the aim of science is to represent the underlying order of the world, science is necessarily devoid of man's evaluative judgements - thus firmly establishing the notion of scientific neutrality.

The Baconian argument, on the other hand, is predominantly epistemological and methodological. Accordingly, the world is only what can be observed. This approach places scientific methodology at its heart:-

"Only what is observed ... and certified by replication and agreement – independently of our desires, value perspectives, cultural and institutional norms and presuppositions, expedient alliances and their interests - can properly serve as evidence for scientific posits and for choosing among scientific theories."64

Thus, science is based on empirical evidence "but surely no value judgments."⁶⁵ Statements of fact do not involve statements of value.⁶⁶ Accordingly, science is an impartial entity, and scientific judgments are made on proper rational and objective grounds rather than individual whims and subjectivities. Consequently, science is seen as a self-sufficient, autonomous body with its own internal dynamic.⁶⁷ Any interference from external values and interests only contaminate scientific processes and threaten its neutrality, impartiality and objectivity. In order to preserve this autonomy, non-scientific values and interests are denied any role in scientific practice. According to Lacey, this notion that science is value free "has long played a key role in the self-understanding and the public image of modern science."68 Claims that science is dependent on individual or organisational contexts are rejected on the basis

⁶² Lacey, H. Is Science Value Free? Values and Scientific Understanding (Routledge; London; 1999) at page 3.

⁶³ MacIntyre, A. After Virtue (University of Notre Dam Press; Notre Dame; 1981) at pages 80-1

⁶⁴ Lacey, H. (1999) at page 4.

⁶⁵ Hempel, C. G. 'Science and Human Values', in Hempel, C. G. Aspects of Scientific Explanation (The Free Press; New York; 1965) at page 91.

⁶⁶A concept otherwise known as the 'Humean schema' – see Hume, D. A Treatise of Human Nature (1740) (Nidditch, P. N. (ed)) (Clarendon Press; Oxford; 1978). ⁶⁷ Lacey, H. (1999) at page 9.

⁶⁸ *Ibid.* at page 1.

that it challenges the legitimacy traditionally enjoyed by the natural sciences. In order to maintain its authority, science is deemed to operate in a vacuum from external influences. Early last century, for example, Poincare wrote:-

"Ethics and science have their own domains, which touch but do not interpenetrate. The one shows us to what goal we should aspire, the other, given the goal, teaches us how to attain it. So they never conflict since they never meet. There can be no more immoral science than there can be scientific morals."⁶⁹

On a similar note, Luhmann comments that:-

"[t]he intervention of personal qualities and circumstances are treated as disturbing noises and, like other 'accidents', eliminated if they do not lead to valuable discoveries of truths or falsities."⁷⁰

Science is thus de-anthropologized.⁷¹ It is removed from its context and operates in an abstract sphere. It operates on the basis that there are truths 'out there' waiting to be discovered, which, once discovered, will form a certain and permanent part of knowledge.⁷² The scientific value of such knowledge is dependent on whether is can be supported by empirical fact.⁷³ On a purely philosophical level then, the scientific position can be described as subscribing to a realist or objectivist ontology, advocating the claim that "a world exists independent of percipient human observers".⁷⁴ It is on this basis that scientific risk assessment operates.

Heightened awareness of the problems of decision-making in relation to the unknown future has resulted in increased demand for a framework of decision analysis. In response to this a model of decision-making known as risk assessment has developed. Despite the fact that risk assessment has evolved with time, it continues to display a

⁶⁹ Poincare, H. The Value of Science (Dover; New York; 1958) at page 12.

⁷⁰ Luhmann, N. *Ecological Communication* (Polity Press; Cambridge; 1989) at page 77.

⁷¹ *Ibid.* at page 78.

⁷² Weinberg, S. 'The Revolution that Didn't Happen' (1998) 45(15) New York Review of Books 48-52.

⁷³ Lakatos, I. 'The Methodology of Scientific Research Programmes', in Worrall, J. and Currie, G. (eds) *Philosophical Papers Vol.1* (Cambridge University Press 1978) at page 1.

⁷⁴ Rosa, E. A. (1998) at page 18.

fundamental trait of early models – making an explicit claim to rationality in that it seeks to reduce risk to numeric expression. The quantitative and reductive nature of risk assessment demonstrates close ties with economic and utility theory which rely on "a cardinal numerical scale"⁷⁵ of magnitude and likelihood.⁷⁶ Risk is, accordingly, a problem of measurement.⁷⁷ These deeply embedded features are considered rational scientific practice, allowing risk assessment to produce objective results on the basis of positivism and logical empiricism.⁷⁸

For Rosa, objective science is the 'bedrock' of risk assessment.⁷⁹ Objective risk assessment, in the scientific sense, is concerned primarily with the prediction of future events from numerical data yielded from past events, and is based on the common belief that 'anything can be proved with statistics'.⁸⁰ A report published by the Medical Research Council Institute for Environment and Health categorises probabilistic assessment into either classical frequentist or Bayesian.⁸¹ They differ not only in their underlying philosophy, but also in the way in which statistical evidence is incorporated into assessment.⁸²

In the classical view, the probability of a future event is defined by the frequency with which the event will occur, based upon a series of repeated observations. Conventionally, if an inadequate historical database of observation exists, mathematicians and economists turn to the Bayesian approach, which expresses probability in terms of the relative likelihood of different outcomes, based on the best

 ⁷⁵ Stirling, A. 'Risk, Uncertainty and Precaution: Some Instrumental Implications from the Social Science', in Berkhout F. *et al* (eds) Negotiating Environmental Change: Perspectives in Environmental Social Science (Edward Elgar; Cheltenham; 2003) pages 33-76, at page 38.
 ⁷⁶ See Starr, C. 'Social Benefit Versus Technological Risk: What is Our Society Willing to Pay for

⁷⁶ See Starr, C. 'Social Benefit Versus Technological Risk: What is Our Society Willing to Pay for Safety?' (1969) 165 Science 1232-1238.

⁷⁷ See, for example, Kates, R. W. and Kasperson, J. X. (1983) at page 7029:- "A hazard, in our parlance, is a threat to people and to what they value ... and risk is a measurement of hazard".

⁷⁸ Lowrance, W. W. Of Acceptable Risk: Science and the Determination of Safety (Kaufmann; Los Altos, California; 1976); Rowe, W. D. (1977); Starr, C. (1969).

⁷⁹ Rosa, E. A. (1998) at page 18; see also EU Committee (1999) at page 35.

⁸⁰ Hattis, D. and Smith, J. 'What's Wrong with Risk Assessment?', in Humber, J. M. and Almeder, R. F. (eds) *Quantitative Risk Assessment* (Humana Press; New Jersey; 1987) pages 55-105, at page 81; see also Lee, T. R. 'Perception of Risk – The Public's Perception of Risk and the Question of Irrationality', in The Royal Society Report: *The Assessment and Perception of Risk*, (The Royal Society; London; 1981) pages 5-16, at page 6.

⁸¹ Price, G. M. and Shuker, L. K. (eds) 'Probabilistic Approaches to Food Risk Assessment', Report of a Workshop Held on 8-9 June 1998 (MRC Institute for Environment and Health; University of Leicester; 2000) at page 6.

⁸² Ibid.

available information and the prevailing expert opinion.⁸³ According to the Bayesian model, probability is considered a 'degree of belief',⁸⁴ and, unlike the frequentist approach, places emphasis on judgement as well as available evidence. Bayesian reasoning "is a quantitative means of assessing uncertainty in the light of incomplete evidence",⁸⁵ and is based on the principle that probability can be quantified by taking into account statistical information in the light of what is currently known.

Probability, therefore, is only relative to the knowledge at the time of prediction. Keynes notes that "our estimate of the probability of an event varies not absolutely with the circumstances which actually affect its occurrence but with our knowledge of those circumstances."⁸⁶ Knowledge of an event is dependent on one's conception of that event, rather than on the event itself. As a result, the future is not susceptible to direct objective measurement.⁸⁷ Yet, in spite the fact that probabilistic assessment is informed by subjective risk perception, it is commonly presented as a strictly scientific process whose predictions can be interpreted as objective, certain, and normative calculations.

6.5 Risk assessment: the centrality of scientific quantification

Dealing with risks to human health and safety and to the environment is a complex and ever-evolving discipline. As decisions in modern society have become more intricate, more formal decision making tools have developed,⁸⁸ and there has been widespread recognition that handling risk issues should follow a structured approach known as the 'risk cycle'. Essentially, the risk cycle describes a three-stage model of

⁸³ Jaynes, E. T. 'Bayesian Methods: General Background', in Justice, J. H. Maximum Entropy and Bayesian Methods in Applied Statistics (Cambridge University Press; Cambridge; 1996) pages 1-25; Wallsten, T. 'Measuring Vague Uncertainties and Understanding Their Use in Decision Making', in Von Winterfeldt, D. and Edwards, W. *Decision Analysis and Behavioural Research* (Cambridge University Press; Cambridge; 1986).

⁸⁴ Price, G. M. and Shuker, L. K. (2000) at page 6.

⁸⁵ *Ibid*. at page 21.

⁸⁶ As cited in Keykhah, M. 'The Shape of Uncertainty: Implications for Decision Making' (Economic Geography Research Group; University of Oxford; Oxford; 2002) *Working Papers, WPG 02-03*, at page 6.

⁸⁷ Hattis, D. and Smith J. A. 'What's Wrong With Quantitative Risk Assessment?', in Humber, J. M. and Almeder, R.F. (eds) *Quantitative Risk Assessment* (Humana Press; New Jersey; 1987) 57, at page 65.

⁸⁸ See Covello, V. T. and Merkhofer, M.W. Risk Assessment Methods – Approaches for Assessing Health and Environmental Risks (Plenum Press; New York; 1993).

risk assessment, risk management, and risk communication, and is intended to make a critical contribution to the recognition of potentially hazardous situations as early as possible.⁸⁹ Although a number of different risk cycle models have been developed in the past, all tend to display three principal characteristics – first, science is given a pivotal role in risk assessment; secondly, there is an operative separation of risk assessment from risk management; and finally, risk communication occurs throughout the whole process.⁹⁰

According to the European Commission, the term *risk assessment* is used to describe the evaluation, identification, measurement and prioritisation of risks.⁹¹ The *risk management* stage operates in response to results generated by risk assessment, and involves the weighing up of different policy options, and, if necessary, the implementation of appropriate control measures.⁹² *Risk communication* is ongoing throughout the risk cycle, and is an interactive process of exchanging information and opinions between actual or potential stakeholders.⁹³

Although each component of the risk cycle are important in ascertaining the manner in which the future is perceived and controlled, this part focuses specifically on the process of risk assessment because of its fundamental role in distinguishing between risk and uncertainty. Risk assessment has grown to become a recognised discipline in itself. From a historical perspective, it has been traced back to the ancient Babylonians.⁹⁴ Nevertheless, it is more widely accepted that the conventional process of risk assessment emerged in the mid-twentieth century. Although risk is a much older concept, risk assessment is associated with the 'professionalization' of risk,⁹⁵ marking a transition from the lay discourse of risk to an expert-driven discourse. Simultaneously, this shift elevates quantitative approaches to the measurement of risk,

⁸⁹ EU Committee of the American Chamber of Commerce in Belgium, Position Paper on a Comprehensive Risk Analysis Process (EU Committee; Brussels; 1999) at page 19.

⁹⁰ Ibid.

⁹¹ *Ibid.* at page 18.

⁹² *Ibid*.

⁹³ Ibid.

⁹⁴ Mehta, M. D. 'The Social Construction of Science, Risk and Expertise' (March 2002) Canadian Chemical News 28-30, at page 29; see also, Plough, A. and Krimsky, S. 'The Emergence of Risk Communication Studies: Social and Political Context' (1987) 12(3/4) Science, Technology, & Human: Special Issue on the Technical and Ethical Aspects of Risk Communication 4-10, at page 5; and Covello, V. T. and Mumpower, J. 'Risk Analysis and Risk Management: A Historical Perspective' (1985) 5(2) Risk Analysis 103-120.

⁹⁵ Plough, A. and Krimsky, S. (1987) at page 5.

and, despite an attack on its legitimacy by sociological theory, this form of risk assessment remains the principal means by which risk is defined and understood. And, as risks increasingly emanate from techno-scientific activities, so risk assessment becomes more firmly fixed in the realm of scientific knowledge.

By and large, it is agreed that the birth of quantitative risk assessment was induced by the emergence of post-war decision analysis. There is, however, lacking consensus with regard to the period during which risk assessment came to the forefront of decision-making in the face of uncertainty. Some trace its appearance to the mid-1940s,⁹⁶ others to the late 1940s,⁹⁷ even as late as the early 1950s.⁹⁸ Whichever is most accurate, the collective opinion points to risk assessment as a response to post-war insecurity, the influence of military strategy, and the realisation of nuclear capabilities.

In their article, *The Emergence of Risk Communication Studies*, Plough and Krimsky claim that contemporary risk assessment is derived from a variety of quantitative approaches introduced in the late 1940s to aid economic and military decision-making.⁹⁹ Despite the fact that they trace the beginnings of transition to the expert-centred field to as far back as the eighteenth century, scientifically-based quantitative risk assessment is deemed to have arisen following World War II.¹⁰⁰ In the two decades ensuing, a crude mathematical model gradually infiltrated the social sciences, and by the 1960s, a fully-developed decision-making methodology, based on the concept of rational choice, had come to command the risk arena.

Strydom is rather more specific about the origins of quantitative risk assessment. Accordingly, early models emerged as the by-products of the development of the nuclear industry and debate about its safety. The first risk study was conducted in the United States in 1957 by the Brookhaven National Laboratory, known as the Brookhaven or Wash-740 Report, commissioned by the US Atomic Energy Commission. Essentially, the report set out to determine the likelihood that fission

⁹⁶ Burton, I. et al, The Environment as a Hazard (Oxford University Press; New York; 1978).

⁹⁷ Plough, A. and Krimsky, S. (1987) at page 5.

⁹⁸ Strydom, P. (2002) at page 13.

⁹⁹ Plough, A. and Krimsky, S. (1987) at page 5.

¹⁰⁰ Ibid.

products might be released from a nuclear plant,¹⁰¹ the levels of exposure or contamination which cause injury to people or damage to property,¹⁰² and the number of deaths or types of injury, or costs in damaged property that could ensue in the event of radiation exposure.¹⁰³

Interestingly, it begins by placing the risk assessment in the context of heightened risk awareness in the post-war era:-

"It might be supposed, because the essential fuel in a nuclear power reactor is the same as that in atomic bombs, that gross malfunctioning in power reactors could possibly lead to a devastating explosion similar to those produced by A-bombs. Such is not the case."¹⁰⁴

From the outset, it is evident that the principal intention of the study is to restore public confidence in the nuclear industry.¹⁰⁵ Given that public perception is deemed paramount, it is perhaps surprising that the report is written wholly from a scientific perspective, without recourse to lay opinion.¹⁰⁶ This early example scientific domination in the risk debate continues to form the basis of contemporary risk analyses.

The alliance between nuclear risk assessment and quantification was later drawn upon and confirmed by British physicist Farmer.¹⁰⁷ In his paper entitled *Reactor Safety and Siting: A Proposed Risk Criterion*, Farmer proposed that a model of safety analysis based on probability theory be employed to assess the risks associated with the construction of a nuclear reactor plant. Demonstrating uttermost allegiance to its

¹⁰¹ Atomic Energy Commission, Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants: A Study of Possible Consequences if Certain Assumed Accidents, Theoretically Possible but Highly Improbable, Were to Occur in Large Nuclear Power Plants, WASH-740 (U.S. Atomic Energy Commission; Washington D.C.; March 1957) at page 1.

¹⁰² *Ibid*.

¹⁰³ *Ibid*.

¹⁰⁴ *Ibid*.

¹⁰⁵ *Ibid.* Foreword given by Chairman of the Atomic Energy Congress of the United States, at pages vii-ix.

¹⁰⁶ the Study Group was comprised entirely of scientists and engineers, see list of participators on page viii.

¹⁰⁷ Farmer, F. R. 'Reactor Safety and Siting: A Proposed Risk Criterion' (1967) 8(6) Nuclear Safety 539-548.

scientific roots, the model relies heavily on the measurement of risk.¹⁰⁸ Farmer states that "[t]he logical way of dealing with this situation is to seek to assess the whole spectrum of risks in a *quantity-related manner*".¹⁰⁹ It is critical to note that an explicit link is made between the quantification of risk and the avoidance of excessive complexity in decision-making.¹¹⁰ The reduction of risk to a one-dimensional quantity facilitates the simple analysis and comparison of risk.

Similarly, the underlying concept of Rowe's *Anatomy of Risk*¹¹¹ is that risk assessment is based solely upon quantification.¹¹² Accordingly, risk is a component of magnitude and probability,¹¹³ and there are three stages to the risk measurement process. Drawing the first from Kates' *Risk Assessment of Environmental Hazards*,¹¹⁴ and the latter two from the works of Otway,¹¹⁵ Rowe explains that the risk assessment process comprises of risk identification, risk estimation, and risk evaluation. Risk identification is a preliminary diagnostic stage, involving the observation and recognition of a new risk. The risk estimation stage is marked by the quantification of the likelihood of an identified risk and the severity of its consequences. Finally, risk evaluation is a process by which acceptable levels of risk to individuals or to society are developed.

Despite the fact that the European Commission claims that the development of quantitative approaches owes much to European scientists, statisticians and philosophers,¹¹⁶ it also maintains that most, if not all models of risk assessment are

¹⁰⁸ *Ibid*. at page 540.

¹⁰⁹ Ibid. at page 539, emphasis added.

¹¹⁰ *Ibid.* at page 547.

¹¹¹ Rowe, W. D. (1977).

¹¹² *Ibid*. at page 3.

¹¹³ *Ibid.* at page 24.

¹¹⁴ Kates, R. W. 'Risk Assessment of Environmental Hazards', Scientific Committee on Problems of the Environment (SCOPE) Report No.8 (International Council of Scientific Unions; Paris; 1976).

¹¹⁵ See Otway, H. J. 'Risk Estimation and Evaluation' in *Proceedings of the International Institute for Applied Systems Analysis Planning Conference on Energy Systems, IIASA-PC-3*, (International Institute for Applied Systems Analysis; Austria; 1973); and Otway, H. J. 'Risk Assessment and Social Choices', in *IIASA Research Memorandum RM-75-2* (International Institute for Applied Systems Analysis; Austria; February 1975) at page 5.

¹¹⁶ EU Committee (1999) at page 36. See for example, the works of Laplace, P. S. *A Philosophical Essay on Probabilities* (Dover; New York; 1951) which established the basis of probability theory. See also Ramsey, F. P. *Truth and Probability – The Foundation of Mathematics and Other Logical Essays* (K. Paul, Trench, Trubner & Co.; London; 1931); and Di Finetti, B. 'La Prevision, Ses Lois Logiques, Ses Sources Objectives' (1937) 7 *Ann. Inst. Henri Poincare* 1-68 which created a framework for decision making in the face of uncertainty.

based on a report published by the US National Academy of Science National Research Council ('the NRC' hereafter).¹¹⁷ The report, *Risk Assessment in the Federal Government: Managing the Process* (also known as *the Red Book*)¹¹⁸, considers the problem of chemical carcinogenicity, and establishes a four-stage model of risk assessment, including hazard identification, hazard characterisation, exposure assessment, and risk characterisation.¹¹⁹ Although the framework was initially intended to deal with human health assessment, it was later adopted for environmental risk assessment. Arguably, the Red Book has provided the template for subsequent risk assessment models. Scientific assessment has since become an 'entrenched methodology',¹²⁰ and it is universally accepted as the dominant method of risk analysis. Underpinning models of scientific risk assessment are notions of objectification and an empiricist culture, and the assumption that everyone sees the same thing in the same way.

In particular, the NRC was asked to determine whether there should be a single, centralised risk assessment process in federal government. It was suggested that such an arrangement would reduce the influence of policy-makers, thus minimising the possibility of risk assessment being manipulated so as to satisfy predetermined policy. Perhaps most notably, the report highlighted the profound schizophrenia upon which the risk cycle is based by emphasising the importance of a conceptual distinction between risk assessment and risk management. This intellectual boundary separates the *scientific* foundations of risk assessment, and the *political* footing of risk management.¹²¹ As such, science and politics are distinct processes. Whereas risk *assessment* is concerned with the production of scientifically-certain constructions of risk, risk *management* is associated with the social authorisation of risk. The dichotomy serves to emphasise that the risk assessment stage is crucial so as to obtain the requisite scientific basis for regulatory decision-making.¹²² As is demonstrated

¹¹⁷ EU Committee (1999) at page 37.

¹¹⁸ National Research Council (NRC) Risk Assessment in the Federal Government: Managing the Process (National Academy Press; Washington D.C.; 1983). ¹¹⁹ Ibid. at page 84.

¹²⁰ Jaeger, C. C. *et al* (2001) at page 89.

¹²¹ Jasanoff, S. Serviceable Truths: The Legitimation of Uncertainty under American Law; Cardiff Social Science Seminar Series 2003-4, 13th November 2003.

¹²² Rodricks, J. V. 'Historical Perspective of Risk Assessment and Review of Steps in the Process', in Food Safety Policy, Science, and Risk Assessment: Strengthening the Connection: Workshop

below, the dichotomy not only has significant repercussions on the application of the precautionary principle, but is also impossible to maintain. At present however, it is necessary only to draw attention to the ostensible scientific and apolitical nature of risk assessment.

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Proceedings (Institute of Medicine, Food and Nutrition Board; Washington D.C.; 2001) 25-27 at page 26.

Chapter Seven

The societal dimensions of risk prediction

7.0 Introduction

This chapter builds on the finding in the previous chapter that risk assessment reflects the normative assumption of control, providing an account of the coexistence of complexity with reductionist simplicities evident in applied science. Whereas, in Chapter Five, it is shown that reductionist epistemic commitments pervade mainstream 'sound science' and scientific risk assessment, this chapter points to the limits of predictability, or 'intellectualised control'.¹ It does this on the basis of the traditional distinction made between 'science' and 'society', and the resultant institutionalised separation of narrowly scientific concerns from broader contextual issues.² Despite the fact that reductionism and notions of 'linear thinking' have been long-standing idioms of science and risk assessment,³ this chapter illustrates that in reality the concept of risk and ethical questions *do* converge. In the words of Wynne:-

"The anointed 'sound science' for such regulatory public science is invariably risk assessment, which, as many analysts have recognised, is always represented as if it is open scientific knowledge, but is always framed in various contextual and reductionist ways."⁴

This chapter offers an alternative approach to the prevalent epistemic understanding of risk that it has objective, rather than constructed, meanings. It turns to sociological analyses of risk that demonstrate a more reflexive and culturally extensive approach to the subject. Theorists such as Douglas, Wildavsky, Slovic, Tversky and Kahneman claim that we cannot know the risks we face.⁵ Risk is not a reality; it is only

¹ Wynne, B. 'Reflexing Complexity: Post-genomic Knowledge and Reductionist Returns in Public Science' (2005) 22(5) *Theory, Culture & Society* 67-94, at page 69.

² See Rayner, S. and Cantor, R. 'How Fair is Safe Enough? The Cultural Approach to Social Technology Choice' (1998) 7(1) Risk Analysis 3-9.

³ Wynne, B. 'Reflexing Complexity: Post-genomic Knowledge and Reductionist Returns in Public Science' (2005) 22(5) *Theory, Culture & Society* 67-94, at page 70.

⁴ *Ibid.* at page 83.

⁵ Douglas, M. and Wildavsky, A. B. (1982).

perceived. And, given that its existence is contingent on perception, a number of societal factors affect its construction. Irwin suggests that this social constructivism captures a 'richer and more diverse'⁶ sense of reality than the hegemony of strictly scientific interpretations of risk.

The conflict between the tendency for scientific risk assessment to conceptualise risk as an objective measurement and the constructivist view of risk as subjective and contextually-dependent entity can be described as the 'objective-perceived risk dichotomy'.⁷

This distinction has long been a source of tension in the risk debate, although this simplistic polarization is often misconceived as proposing strictly alternative understandings of risk. This thesis is not intended as a complete dismissal of scientific approaches to risk assessment. Instead, it is designed to bring to attention the fact that, as a result of its inability to communicate the contextual dimensions of risk, purely scientific predictions should be construed in the light of their institutional premises and political-cultural underpinnings.⁸ This thesis does not deny that regulatory decision-making should be rooted in scientific findings. It is inevitable, and indeed desirable, that science informs decision-making.⁹ However, as this thesis argues, the normative interpretation of scientific calculations of risk must be accompanied by an appreciation for the broader values, preferences, attitudes and reasonings that inform definitions of risk.

⁶ Irwin, A. Sociology and the Environment (Polity Press; Cambridge; 2001) at page 159.

⁷ Lee, T. R. 'Perceptions of Risk – The Public's Perception of Risk and the Question of Irrationality', in The Royal Society Report, *The Assessment and Perception of Risk*, A Royal Society Discussion Group Held on 12 and 13 November 1980 (The Royal Society; London; 1981) 5-16, at pages 6-7, emphasis added; for a detailed discussion about the objective-subjective dichotomy, see Rosa, E. A. 'Metatheoretical Foundations for Post-Normal Risk' (1998) 1(1) *Journal of Risk Research* 15-44, at page 17; Agassi, J. 'The Cheapening of Science' (1984) 27 *Inquiry* 167-172.

⁸ Luhmann, N. A Sociological Theory of Risk (Aldine de Gruyter; Berlin; 1993) at page 2; Jaeger, C. C. et al, Risk, Uncertainty, and Rational Action (Earthscan; London; 2001) at page 107; see also Renn, O. 'The Role of Risk Communication and Public Dialogue for Improving Risk Management' (1998) 3 Risk Decision and Policy 5-30.

⁹ Beck notes that, since modern society presents uncertainty that is beyond our reckoning, and given that scientific systems continue to enjoy residual social authority, it is inevitable that decision-making is deemed to be impossible without being based on scientific reasoning (Beck, U. and Willms, J. *Conversations with Ulrich Beck* (Polity Press; Cambridge; 2003) at page 203).

7.1 Social constructivism: two phases

In what is broadly described as the first phase of social constructivism, psychometricians recognised discrepancies between expert risk assessment and public perceptions of risk, and realised that they could be explained by factors other than Accordingly, the cultural context within which risk was empirical evidence. perceived was deemed a significant, although not overriding, factor in the expert-lay dichotomy. By contrast, the emergence of the second phase of social constructivism was marked by the claim that risk perception was solely dependent on cultural context. Unlike the psychometric paradigm, the second phase focuses primarily on collective, rather than individual, responses to risk. It is based on the assumption that, within any society, there exist a number of competing and conflicting cultural rationalities. Here, 'rationality' is used in the normative sense, describing values and beliefs about the way in which society ought to be. Those rationalities generate cultural 'biases' through which risk is defined and understood. Unsurprisingly, given its fixation with the impact of cultural context on perception, the second phase is typically referred to as the 'cultural theory' of risk.

Both phases draw to attention a number of themes – the conflict between objectively observed and subjectively perceived risk, the expert-lay dichotomy, rationality versus irrationality, and quantitative as opposed to qualitative. Collectively, the psychometric and cultural theory paradigms highlight that social constructivism undermines the legitimacy of conventional risk assessment. The crux of the argument is that, if it can be demonstrated that the concept of risk necessarily possesses a psychological or social dimension, scientific risk assessment processes cannot uphold its claims to objectivity and authoritative accuracy. Subjectivity is so inherent in risk perception, it is impossible to achieve an understanding of risk that displays the objective and certain traits assured by scientific method. According to Adams, scientific uncertainty about the physical world and the inherent complexity of risk makes risk an inherently uncertain entity.¹⁰ Perceptions of risk are equivalent to risk

¹⁰ Adams, J. (1995) at page 25.

itself.¹¹ In the words of Slovic, "[h]uman beings have invented the concept of 'risk' ... there is no such thing as 'real risk' or 'objective risk'".¹² Subjectivity turns risk into a phenomenon of 'multiple contingency'.¹³ Attempts to express subjectivities using a conventional assessment framework inevitably produce artificially conflated and incommensurable results.¹⁴ Thus, by virtue of its nature, risk does not lend itself to methods of quantification so traditionally associated with direct observation and risk assessment.¹⁵

Naturally, this has significant implications for the precautionary principle, not least because the risk assessment process upon which it depends is stripped of legitimacy. The failure of risk assessment procedures to convey social complexities undermines conventional assumptions of prediction-and-control and leads me to question the interpretation of narrowly-scientific definitions of risk as prescribing the appropriate mode of risk management. The following accounts challenge the institutional misrepresentation of a distinction between 'science' and 'society', and as a result, undermine the sentiment that risk assessment establishes purely factual, established truths "that no rational informed human could deny".¹⁶

7.2 The contribution of cognitive psychology

Essentially, constructivist theories of risk emerged in response to the recognition that, given the risk statistics available, individual behaviour deviates significantly from that expected. Despite being presented with the same information, individuals had very different interpretations and understandings of risk. This field of inquiry was initially pursued by cognitive psychologists. In particular, one of the earliest studies – How

¹⁶ Wynne, B. (2005) at page 70.

¹¹ Hilgartner, S. 'The Social Construction of Risk Objects: Or, How to Pry Open Networks of Risk', in Short Jr. J.F. and Clarke, L. (eds) *Organizations, Uncertainties, and Risk* (Westview Press; New York; 1992) 39-53.

 ¹² Slovic, P. 'Perception of Risk: Reflections on the Psychometric Paradigm' in Krimsky, S. and Golding, D. (eds) Social Theories of Risk (Praeger; New York; 1992) pages 117-152, at page 119.
 ¹³ Luhmann, N. Risk: A Sociological Theory (Aldine de Gruyter; Berlin; 1993) at page 16.

¹⁴ Stirling, A. On Science and Precaution in the Management of Technological Risk, ESRC Global Environmental Change Programme, Final Report, May 1999 (ESRC; London; 1999) at page 13.

¹⁵ Allen, F. W. 'Towards a Holistic Appreciation of Risk: The Challenge for Communicators and Policymakers', (1987) 12 *Science, Technology, and Human Values* 138-143; Vlek, C. A. 'A Multi-Level, Multi-Stage and Multi-Attribute Perspective on Risk Assessment, Decision-Making, and Risk Control' (1996) 1 *Risk Decision and Policy* 9-31.

Safe is Safe Enough? A Psychometric Study of Attitudes Towards Technological Risks and Benefits – was conducted in the late 1970s by Fischoff, Slovic and Lichtenstein.¹⁷ The participants in the study – 76 members of the Eugene, Oregon League of Women Voters – were asked to evaluate 30 different activities with regard to their perceived benefit to society, their perceived risk, and the acceptability of the current level of risk posed by them. The 'activities' investigated included the consumption of alcoholic beverages, the use of contraceptives, fire fighting, hunting, mountain climbing, the application of pesticides, skiing, smoking, and surgery. Participants were also asked to assess the risk posed by such activities in terms of its voluntariness, immediacy, controllability, newness, the severity of its consequences, the dread associated with it, and the degree to which the risk is known to science and to those exposed.¹⁸

The results showed that, overall, perceived risk declined with overall benefit. There was an overwhelming relationship between perceived benefits and acceptable levels of risk – acceptable levels increasing with the level of perceived benefit to society. Marking a departure from standard models of rational choice, the results suggested participants would be more willing to accept higher levels of voluntary rather than involuntary risk,¹⁹ and there was a positive correlation between the degree of perceived risk and the dread and the severity of consequences associated with it. Perhaps most significantly, the study drew an interesting comparison between expert and lay perceptions of risk. The findings suggested that experts used a much broader range of numerical values when assessing risk than lay participants, and that, unsurprisingly, expert perceptions of risk correlated with technical risk estimates. These findings were confirmed, and developed, in a subsequent study conducted by Slovic *et al.*²⁰ Not only were there significant differences *between* expert and lay

¹⁷ Fischoff, B. *et al* 'How Safe is Safe Enough? A Psychometric Study of Attitudes Towards Technological Risks and Benefits' (1978) 9 *Policy Sciences* 127-152.

¹⁸ *Ibid.* at pages 139-141, see table 1.

¹⁹ See, also Starr, C. Benefit-Cost Studies in Sociotechnical Systems, in Perspectives on Benefit-Risk Decision Making (National Academy of Engineering; Washington; 1972), in particular pages 17-42; see page 30:- "[w]e are loath to let others do unto us what we happily do to ourselves."

²⁰ Slovic, P. et al, 'Facts and Fears: Understanding Perceived Risk', in Schwing, R. and Albers, W. (eds) Societal Risk Assessment: How Safe is Safe Enough? (Plenum Press; New York; 1980) at pages 181-216. For a more recent study upholding these findings, see Allen, F. W. 'Towards a Holistic Appreciation of Risk: The Challenge for Communicators and Policymakers' (1987) 12 Science, Technology and Human Values 138-143 which outlines a study conducted by the U.S. Environmental Protection Agency into the pattern of differences in risk estimates – for full study see U.S.

perceptions, but also *amongst* experts and the lay population. The most significant question to emerge from both studies was – how can these differences in risk perception be accounted for?²¹

In an article attempting to address these issues, Kahneman and Tversky examined decision-making in the face of risk, and argued that differences in risk perception could be explained in terms of prospect theory – which espouses that individuals tend to be risk prone when focusing on potential gains, and risk averse when focusing on potential losses.²² For many individuals, risk does not have a linear relationship with the probability and severity of consequences. Instead, the way in which individuals perceive the probability and severity of risk will depend upon a number of contextual circumstances. Those circumstances (or 'persuasive effects'²³) were used to explain why choices made between risky prospects were inconsistent with expected utility theory. More specifically, Kanheman and Tversky claim that the 'certainty effect' and the 'isolation effect' lead to decisions that do not obey the rational model of economic behaviour. The certainty effect explains the tendency for individuals to underweight outcomes that are merely probable and overweight outcomes that are considered *certain*.²⁴ The isolation effect accounts for the tendency for individuals to disregard components that alternative options share, focusing only on those components that distinguish them, in order to simplify the choice between alternatives.²⁵ Both the certainty and isolation effects may produce inconsistent preferences and decision-making. This is further illustrated by Kahneman and Tversky's 'weighting function'. Accordingly, probabilities are replaced by more general weights. Losses and gains are assigned a value. Rather than following a strict linear pattern, the value function is S-shaped – it is generally concave for gains and convex for losses. Interestingly, the value function is steeper for a loss than it is for gains, suggesting that the distress suffered as a result of economic loss outweighs the pleasure associated with gaining the same amount.²⁶ The value of each outcome is

Environmental Protection Agency, Unfinished Business: A Comparative Assessment of Environmental Problems (Washington DC; 1987).

²¹ Jaeger, C. C. *et al* (2001) at page 183.

²² Kahneman, D. and Tversky, A. 'Prospect Theory: An Analysis under Risk' (1979) 47(2) *Econometrica* 263-292.

²³ *Ibid.* at page 263.

²⁴ *Ibid.* at pages 265-267.

²⁵ *Ibid.* at pages 271-273.

²⁶ *Ibid.* at page 279.

multiplied by a decision weight, further distorting the expected utility model. Decision weights measure the impact of events against the desirability of the outcome. On the whole, decision weights are generally lower than the corresponding probability, except in relation to low probabilities, which are usually overweighted.²⁷

From this study alone, it could be concluded that decision-making is more complex than classic economic and insurance models would suggest. Highlighting the failure of expert-driven conventional risk assessment methods to reflect the intricacy of the concept of risk, Slovic claims that:-

"[m]ore generally, psychometric research demonstrates that, whereas experts define risk in a narrow, technical way, the public has a richer, more complex view that incorporates value-laden considerations such as equity, catastrophic potential, and controllability. The issue is not whether these are legitimate, rational considerations, but how to integrate them into risk analyses and policy decisions."²⁸

Also pointing to the shortcomings of technical analyses of risk, a more specific study on the perception of risk probabilities, conducted by Festinger, examined the way in which individual bias causes clear violations of rational decision-making.²⁹ Festinger noted that there is often inconsistency, or 'dissonance', between the information an individual has and the way in which that individual responds to it. For the purposes of the study, dissonance was defined as "nonfitting relations among cognitions",³⁰ and was itself considered a motivating factor in decision-making. It is worth noting, however, that the individual decision-maker will rarely accept that dissonance plays a part in the process. Instead, the individual will rationalize dissonance as a way of nullifying its significance. For example, statistically speaking, smoking is bad for one's health. Yet a smoker, despite being aware of the evidence, rationalises smoking on the grounds that first, it brings pleasure therefore it is worth taking the risk; secondly, the chances of smoking damaging health are over-exaggerated; thirdly, it is

²⁷ *Ibid.* at page 263.

²⁸ Slovic, P. (1992) at page 150.

²⁹ Festinger, L. A Theory of Cognitive Dissonance (Stanford University Press; Palo Alto, California; 1957).

³⁰ *Ibid.* at page 3.

impossible to avoid all dangers in life; and finally, to stop would encourage excessive eating and weight gain, thus creating a health risk of equal severity.³¹ In essence, dissonance explains decision-making that, prima facie, appears logically inconsistent. In reality, dissonance is inevitable. Festinger notes that few issues are clear cut – opinions are invariably contradictory and the production of new information creates dissonance, albeit momentary, with existing knowledge. The existence of dissonance allows for subjectivity to become the driving force behind decision-making.

For Covello, subjective bias is necessary to offset the complexity of risk decisionmaking. In his article entitled The Perception of Technological Risks: A Literature *Review*,³² he claims that "people do not cope well when confronted with risk problems."³³ Drawing upon the works of Sjoberg,³⁴ Slovic *et al*,³⁵ and Tversky and Kahneman,³⁶ Covello claims that, as a result of intellectual limitations and the need to reduce anxiety, risk and uncertainty are often denied and complex risk problems oversimplified.³⁷ In order to simplify risk problems, inferential or judgmental rules, known as heuristics, become significant in the decision-making process, allowing people to reduce complex probabilistic assessment into a more digestible format. Four of the most significant heuristics are identified as:- i) information availability. which explains why past events that can be clearly and immediately recalled are perceived as being more probable than events that are less mentally available;³⁸ ii) the anchoring effect of information, whereby probabilities are adjusted depending on the perceived significance of the data;³⁹ iii) *representativeness*, or the tendency for people to assume that roughly similar events entail the same characteristics and risks;⁴⁰ and iv) the avoidance of dissonance, which compels people to downplay or ignore information challenging their existing beliefs.⁴¹

³¹ *Ibid.* at page 2.

³² Covello, V. T. 'The Perception of Technological Risks: A Literature Review' (1983) 23 Technological Forecasting and Social Change 285-287.

³³ *Ibid.* at page 287.

³⁴ Sjoberg, L. 'Strength of Belief and Risk' (1979) 2 Policy Sciences 39-52.

³⁵ Slovic, P. *et al* (1980) at pages 181-216.

³⁶ Tversky, A. and Kahneman, D. 'Judgment Under Uncertainty: Heuristics and Biases' (1974) 185 Science 1124-1131.

³⁷ Covello, V. T. (1983) at 287.

³⁸ Jaeger, C. C. et al (2001) at page 103; Covello, V. T. (1983) at page 287.

³⁹ Jaeger, C. C. *et al* (2001) at page 103.

⁴⁰ Jaeger, C. C. *et al* (2001) at page 103; Covello, V. T. (1983) at page 287.

⁴¹ Jaeger, C. C. et al (2001) at page 103.

By focusing on the impact of factors beyond those represented in conventional risk calculations, the paradigm of cognitive psychology has been able to demonstrate the conceptualisation of risk as a subjective, rather than objective, expression. Individual risk estimation and evaluation are shaped by a number of variables. When faced with the task of interpreting risk probabilities, people come already primed with assumptions and weightings.⁴² As such, qualities ascribed to risk are not merely physical and objective – they are *constructed*. From this perspective, the risk discourse is removed from realism and rooted in a much broader theory of socialisation.⁴³ The basic tenet is that, although scientific knowledge contributes to risk analysis, risk is an aesthetic, political and moral construct, moulded by social frameworks of understanding. And in the words of Luhmann, "[o]nce dissolved into ... social differentiations there is no return to the innocence of primary observation."⁴⁴

7.3 Cultural theory

Essentially, the second phase of social constructivism is based on the same notion that risk is a social rather than physical entity. However, whereas psychometric formulations of risk are dependent on an array of factors, ranging from the degree to which risk is assumed voluntarily to the immediacy of consequences, cultural theory considers the pivotal factor in the definition of risk to be cultural context.

Cultural theory has been described as the most comprehensive approach to risk,⁴⁵ tackling an impressive breadth of risk issues – from the public perception and selection of risk, to scientific objectivity and rationality.⁴⁶ Labelled "the most directly influential presentation of constructivism in the environmental and risk field",⁴⁷ Douglas and Wildavsky's *Risk and Culture*⁴⁸ attacks the realist position, aiming to "dispose of the contention that selection of dangers could be determined by direct

⁴² Douglas, M. Risk and Blame: Essays in Cultural Theory (Routledge; London; 1992) at page 58.

⁴³ Luhmann, N. (1993) at page 3.

⁴⁴ *Ibid.* at page 17.

⁴⁵ Rosa, E. A. (1998) at page 21.

⁴⁶ Krimsky, S. and Golding, D. (1992) at page xv.

 ⁴⁷ Strydom, P. Risk, Environment and Society (Open University Press; Buckingham; 2002) at page 50
 ⁴⁸ Douglas, M. and Wildavsky, A. B. Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers (University of California Press; Berkeley; 1982).

assessment of the physical evidence."⁴⁹ They begin their book with a question and an answer – "Can we know the risks we face now and in the future? No, we cannot".⁵⁰ Accordingly, there are no *real* risks in the 'objective observation' sense. Risk can only exist in the collective consciousness of cultures. It is an 'extraordinarily' constructed concept, and should be seen as the product of both knowledge and consent about future prospects.⁵¹ Notably, knowledge and consent about future prospects are determined by social structures within the cultural framework. Thus, risk can be said to be a *cultural* phenomenon, not a physical one.⁵² For Douglas and Wildavsky, this is the most significant problem with scientific risk analysis – it removes risk from its cultural context. It is upon this plane that expert and non-expert approaches to risk lies in the fact that non-expert approaches do not attempt to conceal the influence of cultural context. Of expert approaches, Douglas and Wildavsky claim that it is "a travesty of rational thought to pretend that it is best to take value-free decisions in matters of life and death."⁵³

Recognising a pattern of responses to risk, Douglas and Wildavsky developed a typology to explain the correlation between risk perception and cultural background. Essentially, drawing on Douglas' earlier works, they proposed that the variability of individual responses to risk can be explained in terms of two dimensions of sociality⁵⁴ - grid and group. The first dimension, the *grid*, reflects the extent to which an individual's life is constrained by externally imposed conditions. The second dimension, the *group*, reflects the degree of social solidarity, or the extent to which an individual is involved in collective activities. The grid dimension is represented on a vertical axis, and the group dimension on a horizontal axis. At the top of the vertical axis, human behaviour is prescribed, and constrained by restrictions imposed by the social order. At the bottom, there are no externally prescribed constraints on choice. Running from left to right on the horizontal axis, human behaviour becomes less individualistic and more collectivist as the extent to which individuals are driven or restricted by their commitment to the social unit increases. At the point where the two

⁴⁹ *Ibid.* at page 14.

⁵⁰ *Ibid.* at page 1.

⁵¹ *Ibid.* at page 5.

⁵² *Ibid.* at page 73.

⁵³ *Ibid*.

⁵⁴ Thompson, M. et al, Cultural Theory (Westview Press; New York; 1990) at page 5.

axes meet, human behaviour is divided into four segments symbolizing four different rationalities. Diagrammatically, the typology is represented in the following way:-



Figure 1. Grid-group diagram created on the basis of the work of Douglas, M. and Wildavsky, A. (1982).

It is worth noting that Douglas and Wildavsky's initial typology has since been developed and refined, although subsequent models have tended to replicate the four-fold categorisation.⁵⁵ Essentially, the four types of sociality represented present four difference cultural filters through which individuals perceive and understand the notion of risk. First, the low grid/high group *egalitarian* culture views the emergence of environmental hazards as punishment for 'technocratic hubris' and a failure to respect the forces of nature. It demonstrates a strong group loyalty, upholds democratic decision-making, and has little respect for externally imposed rules. As a result of its low grid position, there is little role differentiation amongst individuals in egalitarian society. Since relations between individuals are ambiguous, it is difficult to resolve internal conflict. Individuals tend only to be able to exert control over others when claiming to speak on behalf of the collective.⁵⁶ Environmental pressure groups and religious sects commonly demonstrate egalitarian traits.

Low grid/low group *individualists* are 'self-made' people, free from the control of others, exerting control over their own environment. They maintain that the environment is robust enough to protect itself, however, in the face of uncertainty, the best course of action is to exercise power over nature by encouraging the use of man-

⁵⁵ Schwarz, M. and Thompson, M. Divided We Stand: Re-defining Politics, Technology and Social Choice (University of Pennsylvania Press; Pennsylvania; 1990); and Thompson, M. et al (1990).

⁵⁶ Thompson, M. et al (1990) at page 6.

made science and technology to maximise human defences against the unpredictable future.

High grid/high group *hierarchists* believe that everything, including the state of nature, is subject to their control. Unsurprisingly, such cultures exhibit hierarchical social relationships, possess strong group boundaries and yield to externally imposed constraints. In stark contrast to the egalitarian position, hierarchy "has an armoury of different solutions to internal conflicts, [including] upgrading, shifting sideways, downgrading, resegregating, redefining."⁵⁷ This exercise of authority is justified on the ground that role differentiation promotes a harmonious lifestyle.

Finally, the high grid/low group *fatalists* have minimal control over their own lives and are resigned to fate, adopting a *laissez-faire* attitude; they "continue to read The Sun, watch videos, drink lager and buy lottery tickets; *que sera sera*."⁵⁸ According to the fatalistic way of life, individuals are subject to external constraints, and are prevented from joining the group responsible for exerting control over them.⁵⁹

Thus, individuals confront risk differently according to the cultural filters through which they perceive it. Perrow claims that this relativity is derived from differences in the underling cultural rationality.⁶⁰ Cultural rationality is embedded in social and cultural values, forming the basis of decision-making without us even knowing about it.⁶¹ Crucially, cultural rationality is described as being *pre*-scientific.⁶² As a result, the significance of cultural context goes unrecognised in scientific risk assessment. As Jasanoff rightly points out, cultural biases penetrate so deeply into risk assessment

⁵⁷ As cited in Thompson, M. et al (1990) at page 6.

⁵⁸ Adams, J. 'A Richter Scale for Risk?: Scientific Management of Uncertainty Versus Management of Scientific Uncertainty' (1998) 23(2) *Interdisciplinary Science Review* 146-155, at page 148.

⁵⁹ Douglas, M. Cultural Bias (Royal Anthropological Institute; London; 1978) at pages 202-3 and 207.

⁶⁰ Perrow, C. Normal Accidents: Living with High-Risk Technologies (Basic Books; New York; 1984) at page 324.

⁶¹ *Ibid.* at pages 315-6.

⁶² See Kaprow, M. L. 'Manufacturing Danger: Fear and Pollution in Industrial Society' (1985) 87(2) American Anthropologist 342-356: see page 343 where it claims that cultural biases in modern society are as pre-scientific as those in tribal society.

that it is impossible to isolate any phase of the assessment process as *purely* scientific.⁶³

7.4 The shortfalls of social constructivism

Unfortunately, despite offering compelling criticism of the conventional quantification of risk, constructivist insights often fail to recognise that the theory of relativism is unlikely to penetrate the scientific realm unless it goes further than simply highlighting the abstract notion of the diversity of risk perception. The fundamental flaw with relativity theory is that it endorses perceptions of risk "with much the same academic detachment that we appreciate divergent perceptions of beauty in museums of ethnic art."⁶⁴ Those advocating the theory of relativism appear content that they have successfully demystified the concept of risk.⁶⁵ Apparently, it is enough simply to expose the part played by subjectivity in risk decision-making and to deny the 'objectivists' any legitimate claim to the truth. However, Rayner concedes that:-

"[w]e have had our fun exposing the smug pretensions of positivist science to privileged knowledge of the world, but unless we can do a better job the last laugh will rightly be on us."⁶⁶

Disappointingly, neither psychometric nor cultural theories of risk go any further than creating heightened awareness of the inability of scientific risk assessment to cope with the multi-dimensional nature of risk, its focus on subjectivity is equally problematic.⁶⁷ As it stands, the rational quantitative approach to risk assessment

⁶³ Jasanoff, S. 'Cultural Aspects of Risk Assessment in Britain and the United States', in Johnson, B. and Covello, V. T. (eds) *The Social and Cultural Construction of Risk: Essays on Risk Selection and Perception* (Reidel Publishing; Dordrecht; 1987) chapter 15, at page 392.

⁶⁴ Rayner, S. (1987) at page 6.

⁶⁵ See Latour, B. and Wolgar, S. Laboratory Life: The Social Construction of Scientific Facts (Sage; Beverly Hills, California; 1979)

⁶⁶ Rayner, S. (1987) at page 6.

⁶⁷ See Wynne, B. 'Public Perceptions of Risk', in Aurrey, J. (ed) *The Urban Transportation of Irradiated Fuel* (Macmillan; London; 1984) at 246-259; Marris, C. *et al* 'Exploring the Psychometric Paradigm: Comparisons Between Aggregate and Individual Analyses' (1997) 17 *Risk Analysis* 303-312; Plough, A. and Krimsky, S. 'The Emergence of Risk Communication Studies: Social and Political Context' (1987) 12 *Science, Technology, and Human Values* 4-10.

cannot be reconciled with the theory of 'irrational' risk perception. The antagonism between the two raises an interesting dilemma. On the one hand, full quantification of risk into a one-dimensional figure is fundamental in dealing with the practicalities of collective decision-making. In this sense, quantification is advantageous because it allows for the numerical comparison of alternative, seemingly dissimilar, hazards. Although quantification is crude and simplistic, it is a response to the administrative demand for more formal and regimented risk assessment,⁶⁸ and it operates in a universally recognisable language.⁶⁹ On the other hand, attempts to codify risk perception using an "artificially precise uni-dimensional scale"⁷⁰ inevitably produce unrealistic and blinkered results. In other words, the narrowness of scientific risk assessment is its weakness as well as its strength. As Jaeger *et al* points out:-

"The broadness of the dimensions that people use to make judgments and the reliance on intuitive heuristics and anecdotal knowledge make it hard, if not impossible, to aggregate individual preferences and to find a common denominator for comparing individual risk perceptions."⁷¹

Klinke and Renn also observe that:-

"[t]o focus on the objectivist perspective only ignores the social processing of risk information; to rely only on the constructivist perspective may lead to more fatalities and other adverse effects than necessary under the condition that there are only limited societal resources available for risk reduction."⁷²

Thus, there is an underlying tension between the simultaneous need for, and the impossibility of, objective quantification of risk. Relativism cannot be ignored in the

⁶⁸ The Royal Society, *Risk Assessment: Report of a Royal Society Study Group* (Royal Society; London; 1983) at page 111.

⁶⁹ Covello, V. T. Risk Comparisons and Risk Communication: Issues and Problems in Comparing Health and Environmental Risks, in Kasperson, R. E. and Stallen, P. M. (eds) *Communicating Risk to the Public* (Kluwer; Dordrecht; 1991) 79-124.

⁷⁰ Wynne, B. (1984) at page 249

⁷¹ Jaeger, C. C. *et al* (2001) at pages 106-7

⁷² Klinke, A. and Renn, O. A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies (2002) 22(6) *Risk Analysis* 1071-1094 at 1073; see also Shrader-Frechette, K. S. *Risk and Rationality: Philosophical Foundations for Populist Reforms* (University of California Press; Berkeley, Los Angeles; 1991).

risk equation; however, the ultimate issue is to determine its proper place in risk analysis. It is clear, though, that it is impossible to pursue a wholly constructivist approach. In the words of Rosa:-

"if we presuppose an entirely constructed or culturally conditioned reality, we are also presupposing a reality independent of all social constructions that provides the raw material out of which the constructions are formed."⁷³

Socially constructed reality can only be born of an ontologically objective reality. As Searle puts it, "socially constructed reality presupposes a nonsocially constructed reality."⁷⁴ In other words, socially constructed facts cannot exist without brute facts. Our constructed perceptions of risk are necessarily activated by an independent, external source.

On a more practical note, the '*risk equals perceived risk*' argument is problematic because, in maintaining that risks must be perceived in order to exist, it discards the possibility that a potential hazard exists which is not considered to be a 'risk' because it has not yet been perceived. Thus, although it has been recognised that the linearity of a purely scientific understanding of risk cannot accommodate its true complexity, it has also been established that theories accounting for this complexity do not satisfy the demand for a practical means of decision making. The obvious tension between the two positions renders them difficult, if not impossible, to reconcile. It is arguable that the discourse of conventional risk assessment needs to be re-examined.⁷⁵ The ultimate challenge, however, is finding a suitable model of decision analysis that does justice to both.

The precautionary principle can perhaps be seen as attempt to frame the future in socially-constructed entity, whilst maintaining the operation of conventionally-structured risk assessment procedures. Indeed, early advocates of precaution were confident that it offered a compromise between the rigidity of the formal discourse of

⁷³ Rosa, E. A. (1998) at page 26.

⁷⁴ Searle, J. R. *The Construction of Social Reality* (Free Press; New York; 1995) at page 191.

⁷⁵ Short, J. F. 'The Social Fabric at Risk: Toward the Social Transformation of Risk Analysis' (1984)
49 American Sociological Review 711-725, at page 722.

science and the flexibility of social construction.⁷⁶ For them, it presented an opportunity to combine aspects of both regimes, establishing a more accommodating dialogue with which the scale and occurrence of future hazards could be interpreted.

Yet, in spite of this optimism, the precautionary principle has remained firmly attached to science in the formal sense, having developed an intimate relationship with reductionist and selective means of articulating the environment. The procedural affiliation between the precautionary principle and the scientific discourse lends further support for the argument that "the origin of 'real' knowledge is laboratory scientific knowledge",⁷⁷ and that scientific construction of risk are innately sovereign over social understandings. Yet, as the following section shows, although discourses of risk beyond formal process of risk assessment criticised for their failure to objectively represent the magnitude and frequency of potential hazards, the scientific discourse itself suffers from the 'unrecognised cultural syndrome'⁷⁸ described above. Wynne observes that:-

"these tacit representations [of objectivity and rationality] protect scientific institutions from critical attention to the unrecognized cultural biases which they embody, project and reproduce in the name of rationality."⁷⁹

7.5 The social process of science: misplaced abstractions and absoluteness⁸⁰

In reality, the notion of scientific observation is far broader than its traditional analogy with visual inspection suggests,⁸¹ and this is also true of risk assessment processes.

⁷⁶ See, for example, Stirling, A. 'Science and Precaution in the Appraisal of Electrivity Supply Options' (2001) 86 *Journal of Hazardous Materials* 55-75. Stirling compares a 'scientific' and a 'precautionary' approach to the regulation of risk, and concludes that the notion of precaution introduces a very different perspective that responds to the inadequacies of narrowly-reductionist scientific assessment, at page 56.

⁷⁷ Wynne, B. (2005) at page 68.

⁷⁸ Wynne, B. 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10(4) *Science as Culture* 445-481, at page 473.

⁷⁹ Wynne, B. 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10(4) *Science as Culture* 445-481, at page 473.

⁸⁰ This heading is inspired by the section in John Adams' *Risk* entitled 'Abstractions and the Fallacy of Misplaced Concreteness' (Adams, J. *Risk* (UCL Press; London; 1995) chapter 11, at page 199).

Stirling notes that a crucial problem that affects risk assessment approaches is the multiplicity of different ways of conceiving 'magnitude' and 'frequency'⁸² based on observations of past events. Observation is contextually dependent. When scientists observe, they are implicitly making reference to what they do know, and also to what they do not know but want to find out. Otherwise, observation would be a relatively meaningless process. Information, derived through observation, is only created if there is a use for it. Necessarily, observation is performed within a particular framework of investigation, it is dependent on a variety of presuppositions and assumptions, and is theory-laden.⁸³ Since it based not only upon the visual inspection but *also* theoretical understandings of the subject, it can be said that scientific observation is a social process that is contingent on predisposed insights.

In his book, Patterns of Discovery,⁸⁴ Hanson set out to demonstrate the importance of individual perception in scientific observation. Following an experimental study, he concluded that "observation of x is shaped by prior knowledge of x".⁸⁵ His study sought to determine whether different theoretical understandings of a subject would bring about different observations of the same object. On the basis of the scientific ideal of objective empiricism, one would, of course, expect the same observation to be recorded in the same way. However, Hanson's study served to illustrate that the scientific ideal is infeasible. He posed the following question:- supposing Johannes Kepler and Tycho Brahe were to watch the sun rise, do Kepler and Brahe see the same thing in the east at dawn?⁸⁶ Hanson stressed that he was not questioning whether they saw the same object. Rather, he was seeking to determine whether Kepler and Brahe had the same experience of the same object given that they had different theories about the sun and its movement. For Kepler, the sun was at the centre of the solar system, and the earth rotated round it annually. Brahe, on the other hand believed that the earth was at the centre of the solar system with, accordingly, the sun rotating round it. When asked what they saw at dawn, Kepler claimed that since it was the earth moving, movement of the sun was only apparent. Unsurprisingly, Brahe maintained that the sun actually moved across the sky. Thus,

 ⁸¹ Barnes, B. et al, Scientific Knowledge – A Sociological Analysis (Athlone; London; 1996) at page 2.
 ⁸² Ibid. at page 7.

⁸³ Ibid.

⁸⁴ Hanson, N. R. Patterns of Discovery (Cambridge University Press; Cambridge; 1958).

⁸⁵ *Ibid.* at page 19.

⁸⁶ *Ibid*. at page 5.

Hanson was able to conclude that observation, even in the narrow sense of the word, is shot through with individual perception. Theories and interpretations are "there' in the seeing from the outset",⁸⁷ and thus produce qualitatively different experiences of the same thing.

Hanson has not been alone in his findings. Kuhn, for example, cites the works of Bruner and Postman⁸⁸ to illustrate influence of prior knowledge on scientific observation.⁸⁹ In this psychological experiment, subjects were given an ordinary pack of playing cards mixed with anomalous cards, such as a black four of diamonds. The subjects were tested on the accuracy with which they identified anomalous cards. The results showed that, initially, subjects saw what they expected to see, taking appreciably longer to recognise anomalies. Since expectations structured what the subjects saw, Bruner and Postman were able to conclude that pre-existing knowledge can cloud the observation of reality. Thus, the idealist notion of objective empiricism cannot always be sustained in reality. Kasper claims that:-

"[the] attraction of objective measures of risk is the apparent elimination of subjective elements in at least one part of the decision-making process. But the attraction is more apparent than real."⁹⁰

The root of the problem seems to lie in the tendency of scientists to perceive objective characterisations of risk as somehow more real or more valid than the concept of subjective interpretations. Despite the public image that science is a dispassionate seeker of the truth, subjective methods play a crucial role in the acquisition of

⁸⁷ *Ibid*. at page 10.

⁸⁸ Bruner, J. S. and Postman, L. 'On the Perception of Incongruity: A Paradigm' (1949) XVIII Journal of Personality 206-223.

⁸⁹ See Kuhn, T. S. The Structure of Scientific Revolutions (University of Chicago Press; Chicago; 1962).

⁹⁰ Kasper, R G. 'Perceptions of Risk and Their Effects on Decision Making', in Schwing, R. C. and Albers, W.A. (eds) Societal Risk Assessment – How Safe is Safe Enough? (Plenum Press; New York; 1980) at page 74. Subjectivity in scientific method was also recognised by Holton who claims that value-judgements pervaded Millikan's research into sub-electrons. See Holton, G. 'Sub-Electrons, Presuppositions and the Millikan-Ehrenhaft Dispute' (1978) 9 Historical Studies in the Physical Sciences 161. See also Wolpert, L. The Unnatural Nature of Science (Faber; London; 1992) at page 95. The position is summarised in Gillispie, C. The Edge of Objectivity (Princeton University Press; Princeton, New Jersey; 1960) at page 150: "Science is created by the scientist".

knowledge. Lacey argues that values "pervade and must pervade"⁹¹ scientific inquiry. If science was purely objective, without contradiction and controversy, the call for research would diminish and scientific progress would "slow to a crawl."⁹² More importantly, a lack of time and resources make it a logistically impossible task to objectively evaluate every new scientific claim – thus, subjectivity is justifiable on grounds of expediency. Scientists must rely on subjectivities to determine which claims to pursue and which ones to discard. If all scientists were objective, then:-

"they would have no alternative but to refuse to hold any view on the correctness or otherwise of these new claims until they had first carried out their own extensive studies."⁹³

Subjectivity is not only necessary, it is unavoidable.⁹⁴ In the absence of consensus and certainty, decisions are necessarily value-laden.⁹⁵ Scientists do not respond blankly to uncertainty.⁹⁶ Instead, they impose meaning upon uncertainty and rationalise decisions according to individual reason. I am not suggesting here that the substitution of value for fact is deliberate, but instead suggesting that subjectivity is so deeply entrenched in the scientific institution that reliance on value rather than fact is presented as objective truth.⁹⁷

The realisation that science is influenced by complex, non-linear relationships between research and subjectivities is exacerbated by symptoms of contemporary 'risk society'⁹⁸ society, which is characterised by pluralism and diversity.⁹⁹ This has

 ⁹¹ Lacey, H. Is Science Value Free? Values and Scientific Understanding (Routledge; London; 1999) at page 259.
 ⁹² Matthews, R. A. J. 'Facts Versus Factions: The Use and Abuse of Subjectivity in Scientific

⁹² Matthews, R. A. J. 'Facts Versus Factions: The Use and Abuse of Subjectivity in Scientific Research', in Morris, J. (ed) *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann; Oxford; 2000) chapter 12, at page 249.

⁹³ Ibid.

⁹⁴ Douglas, M. and Wildavsky, A. B. *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers* (University of California Press; Berkeley; 1982)) at page 63; see also Lowrance, W. W. Of Acceptable Risk: Science and the Determination of Safety (Kaufmann; Los Altos, California; 1976) at page 7.

 ⁹⁵ Waring, A. and Glendon, A. *Managing Risk* (International Thomson Business Press; London; 1998)
 ⁹⁶ Adams, J. 'A Richter Scale for Risk? Scientific Management of Uncertainty Versus Management of Scientific Uncertainty' (1998) 23(2) *Interdisciplinary Science Review* 146-155.

⁹⁷ Lacey, H. (1999) at page 256.

⁹⁸ Reference is made here to Beck's writings on reflexive modernisation and post-industrial risk society - these concepts are discussed in further detail in the following chapter. Beck, U. *Risk Society* (Sage; London; 1992).

inevitably resulted in an increase in the forms of knowledge production, leading to multiplicity of opinion, and a notable shift from 'confident' and 'unproblematic'¹⁰⁰ technological determinism to a state of social 'volatility',¹⁰¹ complexity, and ultimately uncertainty.¹⁰² Whereas traditionally, science was seen as an impenetrable authority, the epistemological core in the reflexive modern phase has become "so crowded with different norms and practices that they cannot readily be reduced to generic methodologies or, more broadly, privileged cultures of scientific inquiry."¹⁰³ The resultant plethora of differing views undermines claims to objectivity and certainty. The upshot is that knowledge is incomplete, contested, subjective and uncertain.¹⁰⁴

It is against this backdrop that scientific risk assessment has come under attack for its discursive practices. In addition to the relativity of scientific observation, the contextual-dependence of scientific analysis becomes apparent in the framing and testing of hypotheses.¹⁰⁵ Wynne observes that policy discourses relating to risk and ethics embody "prior unacknowledged and thus unaccountable yet arbitrary human values and ethical commitments."¹⁰⁶ These subjectivities are culturally entrenched in the 'constitutional framework of deliberate analytical thinking'¹⁰⁷ rather than contingent human biases. Not only does this form an intricate part of scientific observation, but it is also central to the framing of scientific problems. In the words of Hattis and Smith:-

"[i]n designing analyses to produce a few simple numbers to summarize the complex reality of dose-response, how many people may be harmed/helped, and the uncertainties in the estimates provided, the analyst inevitably must convey the impression that *these* are the specific kinds of

⁹⁹ Nowotny, H. et al, Re-Thinking Science – Knowledge and the Public in an Age of Uncertainty (Polity Press; Cambridge; 2001) at page 21.

ion Ibid. at page 30.

¹⁰¹ *Ibid*.

¹⁰² *Ibid.* at page 37.

¹⁰³ *Ibid.* at page 199.

¹⁰⁴ Institute of Science in Society (ISIS) 'Submission to US Advisory Committee on International Economic Policy', Biotechnology Working Group 13 July 2000, <u>www.i-sis.org.uk/prec/php</u>, accessed July 2003.

¹⁰⁵ Wynne, B. (2001) at page 458.

¹⁰⁶ *Ibid.* at page 472.

¹⁰⁷ Ibid.

numbers of interest for the purpose(s) that the analysis is supposed to serve. As with the famous modern art painting of a can of Campbell's soup, the very act of selecting a particular object to put in the picture makes a non-trivial statement that this specific object should be elevated to special status relative to the objects not so portrayed."¹⁰⁸

Weber also notes that the recognition of the existence of a problem "coincides, personally, with the possession of specifically oriented motives and values."¹⁰⁹ Furthermore, the use of specific types of data, analysis techniques and terminology conveys the message that these are the appropriate tools for the decision-making at hand. Judgements about the relative significance of different types of information and methodologies introduce an inescapable subjectivity to the process of risk analysis. It comes as no surprise, therefore, that the risk assessment process has been described as "primarily an 'art' with abundant opportunities for personal interpretation and bias."¹¹⁰ Facts seldom speak for themselves; values shape facts.¹¹¹

The argument that hazard identification reflects human commitments was highlighted by the *amicus curiae* brief submitted in relation to the ongoing WTO Dispute in relation to GM food and crops.¹¹² It argues that principles of selection, emphasis and presentation are crucial in shaping theories about what exists, what happens, and what matters,¹¹³ stating that:-

"[f]raming is integrally related to the possibility of control. Problems that have been framed, with particular causal explanations, can also in principle be managed or solved by addressing the causes so identified. At the same time, framing, by its nature, is also an instrument of exclusion.

¹⁰⁸ Hattis, D. and Smith, J. A. (1987) at page 92.

¹⁰⁹ Weber, M. (Shils, E. and Finch, H. (eds)) The Methodology of the Social Sciences (Free Press; New York; 1949) at page 61.

¹¹⁰ Petts, J. et al, Risk Based Contaminated Land Investigation and Assessment (John Wiley & Sons; Chichester; 1997) at page 301.

¹¹¹ Fischhoff, B. Acceptable Risk (Cambridge University Press; Cambridge; 1981).

¹¹² European Communities – Measures Affecting the Approval and Marketing of Biotech Products WT/DS 291, 292 and 293.

¹¹³ Busch, L. et al, Amicus Curiae Brief Submitted to the Dispute Settlement Panel of the World Trade Organisation in the Case of 'EC: Measures Affecting the Approval and Marketing of Biotech Products', 30 April 2004, at page 16. Full text of amicus available at http://www.lancs.ac.uk/fss/ieppp/WTOamicus, accessed August 2005.

To bring some parts of an issue within a problem frame – to render the issue comprehensible and interpretable – other parts are invariably left out as irrelevant, incomprehensible or uncontrollable."¹¹⁴

This argument that risk assessment encompasses value-laden understandings about appropriate forms and means of governance, institutional capabilities, and cultural aspects challenges the presumptions upon which conventional models of analysis are based. Subjectivity inevitably undermines the rationalist presumption of apodictic knowledge and certainty. Given that determining the likelihood and magnitude of risk involves a strong subjective element,¹¹⁵ scientific risk assessment claims to empirical accuracy are more idealistic rather than realistic. Subjective perception results in a 'conflictual pluralization and multiplicity'¹¹⁶ of risk that is incompatible with the linearity of scientifically observed risk. The scientific principle – 'see no evil, hear no evil, smell no evil, know no evil'¹¹⁷ – is fundamentally flawed because, as it has been shown above, the scientific representation of salient realities exclude more wide-ranging and multivalent questions that are nonetheless critical in the construction of the future.

The question then becomes, of course, how does this affect the operation of precaution? In what way does the exposure of subjectivity in risk assessment impact upon the application of the precautionary principle? In order to answer these questions, it is necessary to emphasise again that the relationship between risk assessment and the precautionary principle is governed by the normative interpretation of risk estimates. The practice of using risk measurements to determine behavioural responses to the future presumes that those statistics are simply objective predictions based on observations of the past. There are two problems here. The first is that risk statistics are the manifestation of more than objective information, and should be interpreted in the light of their context. The second problem, which is considered in the following chapter, is that the practice of projecting the past into the

¹¹⁴ *Ibid.* For a detailed account of the concept of scientific framing, see Wynne, B. 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10(4) *Science as Culture* 445-481, at pages 458-463.

¹¹⁵ Jaeger, C. C. *et al* (2001) at page 118.

¹¹⁶ Beck, U. Risk Society: Towards a New Modernity (Sage; London; 1992) at page 31.

¹¹⁷ Ibid. at page 59.

future as a means of prediction fails to acknowledge that the materialisation of hazards in contemporary society might bear little or no relation to hazards in the past.

The coexistence of complexity and reductionism, and the tension between the humancultural political dimension of risk and institutional discourses reflected by scientific assessment forms the basis upon which theories linking modernity with risk are developed. Ulrich Beck, Anthony Giddens, Niklas Luhmann, and Hans Jonas recognise that hazards in the modern era defy traditional models of uniformity, making it impossible to calculate risk with any degree of certainty.¹¹⁸ The conventional treatment of risk as an objective measurement breaks down with the advent of post-industrial society, exposing rational calculation to the criticism that the materialisation of risk in modern society rarely emulates previously recorded patterns. The next chapter examines this body of risk literature and comments on its relevance to the operation of precaution.

¹¹⁸ See Luhmann, N. Risk: A Sociological Theory (Walter de Gruyter; Berlin; 1993) at page 6.

<u>Chapter Eight</u> <u>Modernity and risk</u>

8.0 Introduction

This chapter focuses on the second criticism of risk assessment cited in Chapter Seven – that hazards in the modern era occur with such irregularity that neither their magnitude nor frequency can be predicted using observations of past events. It illustrates that the emergence of the precautionary principle induces a consideration of broader political issues such as the supremacy of scientific expertise and the relationship between science and responsibility. The aims here are two-fold. First, it provides historical context to the relationship between risk measurement and scientific discourse. Second, it rationalises the emergence of the precautionary principle. It shows that the notion of precaution can be directly associated with the erosion of the unity of scientific knowledge¹ and the realisation that hazards in contemporary society can defy traditional models of prediction. The sociologists cited in this chapter give little, if any, consideration to the precautionary principle.² This chapter remedies this deficiency. It should be noted that, although the structure of Beck's thesis is used as its structure, this chapter has been informed by the works of a number of theorists who have been pivotal in developing a dialogue on risk and modernity.

An exploration of the themes arising from this literature provides a skeleton upon which my examination of the operation of precaution in preceding chapters can hang. In essence, sociological analyses of risk are used here to illustrate the way in which conditions of modernity have accentuated the limits of conventional models of risk assessment – and, as a result, brought into sharp focus the problems with reliance on risk assessment as a normative decision-making tool. The impact of risk literature on the implementation of the precautionary principle is profound and often overlooked.

¹ O'Riordan, T. 'The Cognitive and Political Dimensions of Risk Analysis' (1983) 3 Journal of Environmental Psychology 345-354, at page 347.

² It should be noted that sociological commentators do make reference to anticipatory conduct: Beck, U. and Willms, J. *Conversations with Ulrich Beck* (Polity Press; Cambridge; 2003) refers to the notion of 'current action' at page 135; Luhmann, N. *Risk: A Sociological Theory* (Aldine de Gruyter; Berlin; 1993) cites the 'problem of prevention' at page 29. They do not, however, explicitly refer to the precautionary principle.

Whereas Chapters Six and Seven present the distinction between positivist and constructivist interpretations of risk by distinguishing between the realist scientific position and social constructivism, this chapter approaches the issue from perspective that draws on a temporal distinction between old 'industrial' and new 'risk' societies. This approach is critical in redeeming the process of risk assessment from the criticism that, from a constructivist stance, the operation of precaution falls at the first fence. The logical conclusion to draw from a wholly constructivist perspective is that, given that risk does not exist in any real sense, risk assessment is a futile exercise. Although this deduction is reflective of the argument that risk does not exits beyond its construction, it is neither practical nor realistic to assume that risk assessment is an entirely redundant process. The problem with risk assessment is not its use of estimates deriving from scientific observation. The problem is, in fact, its presentation of risk estimates as objective and, more importantly, the underlying supposition that the results of risk assessment are normative - that is, that risk calculations convey the nature of response demanded in the face of a hazard. The lesson to learn from social constructivism is not necessarily that all forms of risk assessment are useless, but that, because risk quantities have little meaning without reference to their context, they should not be used as sole means of prescribing appropriate risk management. From this standpoint, the application of the precautionary principle ought to be determined by a consideration of risk estimates in their context. The upshot is that a precautionary response to hazards that have been statistically presented as 'scientifically certain' risks might still be suitable. With this in mind, it can be said that portrayals of the precautionary principle as a component of a decision-making algorithm in which precaution applies only in response to unquantifiable threats are unrealistic.

The aim of this chapter is to add substance to the argument that, given that the modern era presents hazards with such irregularity and novelty that they no longer fit with models of prediction, it is important that risk estimates deriving from assessment procedures are contemplated with reference to factors beyond their numerical expression. This is necessary, not simply because abandoning risk assessment procedures altogether is not an option, but also because it will promote a considered and holistic approach to precaution. As Santillo notes, the familiarity of the format of scientific risk assessment results in "widespread neglect of the inherent weaknesses
and assumptions."³ This chapter portrays risk assessment against a backdrop of literature that criticises the practice of projecting observations of the past into the future as a means of risk prediction. It highlights the limits of highly standardised procedures, and depicts the emergence of precaution as a response to uncertain and unknown hazards.

Central to this chapter is the operational relationship between the precautionary principle and scientific knowledge. In particular, this chapter draws attention to the unresolved debate as to whether the notion of 'scientific uncertainty' as contained in the definition of the precautionary principle is in/consistent with formal scientific discourse. This section departs from existing literature on the relationship between precaution and science. Instead of concentrating on the in/compatibility of 'scientific uncertainty' with scientific enterprise, it centres on the difference in the way the precautionary principle and the formal scientific discourse perceive the future. From this perspective, it becomes clear that there is a conceptual conflict between the precautionary principle and science. This discord is crucial in explaining why the ability of the precautionary principle to attribute responsibility for unknown, future impacts of decision-making is restricted by the hegemony of scientific knowledge.

The precautionary principle operates in the face of *scientific uncertainty*.⁴ By virtue of its relationship with scientific knowledge, there has been considerable debate as to whether the precautionary principle is either allied to, or antithetical to, science-based decision-making. For some, the very notion of 'scientific uncertainty' is seen as an implicit statement of the inability of scientific knowledge to foresee the future.⁵ Conversely, other commentators argue that, since the notion of 'scientific uncertainty' represents a stage in the process of acquiring scientific knowledge, the precautionary principle – as a regulatory tool for managing such uncertainty – can be regarded as being entirely consistent with the scientific domain. Mee, for example, claims that the precautionary principle "does not negate the need for science, rather it poses a new challenge to scientists and calls upon them to play a key role in a broader conceptual

³ Santillo, D. *et al* 'The Precautionary Principle: Protecting Against Failures of Scientific Method and Risk Assessment' (1998) 36(12) *Marine Pollution Bulletin* 939-950, at page 945.

⁴ See UNCED Rio Declaration 1992, Principle 15.

⁵ Cameron, J. 'The Precautionary Principle', in Sampson, G. and Chambers, W. B. (eds) *Trade, Environment and the Millennium* (United Nations University Press; New York; 1999) at page 244.

frame in which ethical considerations are of paramount importance."⁶ Stirling considers that "key elements of a precautionary approach are entirely consistent with sound scientific practice in responding to intractable problems in risk assessment".⁷ Similarly, Harremoës *et al* assert that "[t]he precautionary principle has nothing to do with anti-science and everything to do with the rejection of reductionist, closed and arbitrarily narrow science in favour of sounder, more rigorous and more robust science."⁸

However, this chapter adopts a different approach. Although there are valid arguments for interpreting the precautionary principle as either compatible or incompatible with 'scientific *uncertainty*', this chapter draws to attention to the way in which science and the precautionary principle differ in the way they comprehend threats to human health or the environment. Instead of focusing on determining whether or not the notion of scientific uncertainty is in/consistent with science,⁹ it examines the disparity between the way in which scientific and precautionary decision-making perceive hazards that have not yet materialised. Whereas the formal discourse of science regards the future as being a largely calculable controllable entity, the precautionary principle intrinsically recognises that the future cannot be controlled by 'rational' means of quantification. From this perspective, it can be argued that the precautionary principle is adverse to science. The implications of this position are critical to the functioning of the precautionary principle.

Central to the argument is the notion that science is a conceptually inappropriate tool for knowing the future implications of techno-scientific progress in the modern era. It is worth noting here that 'science' is used to describe formal scientific discourse. The

⁶ Mee, L. D. 'Scientific Methods and the Precautionary Principle', in Freestone, D. and Hay, E. (eds) *The Precautionary Principle in International Law: The Challenge of Implementation* (Kluwer Law International; The Hague; 1996) chapter 7, at page 109.

⁷ Stirling, A. 'The Precautionary Principle in Science and Technology', in O'Riordan, T. et al (eds) Reinterpreting the Precautionary Principle (Cameron May; London; 2001) chapter 3, at page 61.

⁸ Harremoës, P. et al (eds) The Precautionary Principle in the 20th Century: Late Lessons from Early Warnings (Earthscan, European Environment Agency; London; 2002) at page 210.

⁹ Note that Cameron describes the 'sound science versus precaution' debate as 'futile', see Cameron, J. 'The Precautionary Principle in International Law', in O'Riordan, T. *et al* (2001) at page 142. Furthermore, Stirling warns against being drawn into the 'dichotomy trap' of polarizing realms of science and precaution, see Stirling, A. (2001) at pages 61 and 66.

'formal scientific discourse' is tied up with notions of 'sound science'.¹⁰ Scientific knowledge is presented as upholding ideals of realism, objectivism, logical empiricism, and rationality. This is achieved through the statistical representation of the future.¹¹

8.1 The emergence of the post-industrial condition

Undoubtedly, Beck's Risikogesellschaft (Risk Society¹²) has been one of the most influential sociological analyses of modernity in the last century - presenting "not only a visionary excursion into our present condition, but also a prophetic perspective on the future".¹³ It traces the emergence of a *new* phase of modernity, and places the origins and consequences of environmental degradation at the heart of the theory of modern society.¹⁴ The study centres on a "break within modernity",¹⁵ enabling society to free itself from the cast of *classic industrial society* and evolve into a new risk society.¹⁶ This transition is "not an option which could be chosen or rejected in the course of political debate,"¹⁷ but rather an inevitable symptom of scientific progress. Alongside this development, Beck notes a simultaneous proliferation of new and undesirable environmental risks, never before experienced. The emergence of such risks marks the beginning of modernity beyond its classical industrial design.¹⁸

¹⁰ See, for example, Edmond, G. and Mercer, D. 'Experts and Expertise in Legal Regulatory Settings' in Edmond, G. (ed) Expertise in Regulation and Law (Ashgate; Hampshire; 2004) chapter 1, at pages 8-9.

¹¹ Luhmann, for example, notes that statements that adhere to the scientific tradition of using statistical procedures appear to be 'scientifically well founded', Luhmann, N. Risk: A Sociological Theory (Walter de Gruyter; Berlin; 1993) at page 214. He goes on to note (at page 215) that the quantification of predictions emphasises their reliability.

¹² Beck, U. Risk Society: Towards a New Modernity (Sage; London; 1992).

¹³ Adam, B. et al, The Risk Society and Beyond – Critical Issues for Social Theory (Sage; London; 2000) at page 1; see also Beck, U. (1992) at page 1.

¹⁴ Goldblatt, D. Social Theory and the Environment (Polity Press; Cambridge; 1996) at page 155.

¹⁵ Beck, U. (1992) at page 9.

¹⁶ Ibid.

¹⁷ Beck, U. 'Risk Society and the Provident State' in Lash, S. et al (eds) Risk, Environmental and Modernity: Towards a New Ecology (Sage; London; 1996) 27-43 at page 31. ¹⁸ Beck, U. (1992) at page 10.

Ulrich Beck's vision of risk society, and the direct link between risk and modernity, is shared by Anthony Giddens,¹⁹ Niklas Luhmann,²⁰ and Hans Jonas.²¹ Beck's *Risk Society* operates on the assumption that there is a distinction between *old* and *new* risks. Essentially, Beck's theory relies on a three-stage model of development – from pre-industrial (pre-modernity), to industrial (modernity), to risk (reflexive modernity) society. *Pre-industrial* society, according to Beck, is characterised by the occurrence of natural hazards which occur independently of human control and as a result of external forces, such as gods, demons or Mother Nature.²² The transition classic *industrial* society is marked by the emergence of dangers that are no longer *solely* attributable to external conditions, but are also the consequences of human behaviour.²³ The birth of risk society, on the other hand, is evident in the emergence of hazards generated by human decision-making alone.

Central to Beck's thesis is the argument that the distinction between industrial and risk society is based on *calculability*. Underlying the industrial-risk dichotomy is the contention that hazards in industrial society are *calculable*,²⁴ whilst those in risk society are *incalculable*.²⁵ Accordingly, hazards typical of risk society do not lend themselves to calculation by way of classic insurance theory. A new category of 'fundamentally ambivalent'²⁶ risk marks the onset of the post-rational era – one which was "not at all perceived by Max Weber."²⁷

¹⁹ Giddens, A. The Consequences of Modernity (Stanford University Press; Palo Alto, California; 1991) at page 4; Giddens, A. Modernity and Self Identity: Self and Society in the Late Modern Age (Polity Press; Cambridge; 1991a) at 122.

²⁰ Luhmann, N. *Risk: A Sociological Theory* (Walter de Gruyter; Berlin; 1993) chapters 1 and 2, specifically pages 26-28.

²¹ Jonas, H. The Imperative of Responsibility: In Search of an Ethics for the Technological Age (University of Chicago Press; Chicago; 1979) at page 6. It is worth noting that, despite the fact that Ulrich Beck is frequently hailed as the most significant theorist in risk literature, Hans Jonas identified that the modern condition presented a new ethical challenge to the traditional control of ecological hazards almost a decade before the first publication of Beck's Risk Society (original publication in German in 1986).

²² Beck, U. World Risk Society (Blackwell; Oxford; 1999) at page 50.

²³ Goldblatt, D. (1996) at page 159.

²⁴ Giddens, A. *The Consequences of Modernity* (Stanford University Press; Palo Alto, California; 1991) at page 2.

²⁵ Beck, U. *Ecological Politics in an Age of Risk* (Polity Press; Cambridge; 1995) at page 77. Incidents in industrial society, says Beck, occur unexpectedly but frequently enough to become substantially predictable, and thus insurable. See also, Beck, U. and Willms, J. *Conversations with Ulrich Beck* (Polity Press; Cambridge; 2003) at page 114.

²⁶ Beck, U. 'The Reinvention of Politics: Towards a Theory of Reflexive Modernization', in Beck, U. et al (eds) Reflexive Modernization, Politics, Tradition and Aesthetics in the Modern Social Order (Polity Press; Cambridge; 1994) chapter 1 at page 9.

²⁷ Ibid.

The transition to risk society emanates from heightened techno-scientific development and the consequent generation of threats that are neither calculable no controllable.²⁸ These 'modernization risks'²⁹ possess unprecedented characteristics, making them distinct from industrial-type hazards. Whereas hazards in the industrial epoch are described as individual, local, sporadic, perceptible, insurable and attributable,³⁰ hazards in the new era are collective, global, systematically produced, uninsurable and non-attributable.³¹

This results in what Beck calls the 'ecological crisis'.³² In contrast with classic models of industrial societies – in which "blame or culpability for threats can be confidently asserted and their statistical likelihood calculated"³³ – risk society throws up risk problems to which there are no unambiguous solutions. Since modern threats do not fit the dimensions of quantitative calculability, the risk calculus collapses.³⁴ Hazards are, in effect, "statistically anonymized"³⁵ and thus scientifically uncertain. Beck explains that:-

"[u]nfortunately, this [risk calculus] model loses its validity in a case like Chernobyl. Chernobyl is a paradigmatic counter-example that bursts through this model of clearly defined accidents in all three [spatial, temporal, and social] dimensions. The way its consequences overleapt geographical and political boundaries was of course spectacular and immediately obvious at the time. But it was just as true of temporal bounds. How does one define an affected population when some of those affected have not yet been born, even today, fifteen years after the

²⁸ Beck, U. (1999) at page 53.

²⁹ Beck, U. (1992) at page 21.

³⁰ In industrial society, environmental hazards "assaulted the nose or the eyes and were thus susceptible to the senses", Beck, as cited in Adams, J. *Risk* (University College Press; London; 1995) at page 179. ³¹ See Beck, U. (1995) at pages 76-7. See also, Beck, U. (1996) at page 31; Halfmann, J. 'Risk Avoidance and Sovereignty' (1988) 8(1) *Praxis International* 14-25; Beck, U. 'From Industrial Society to Risk Society: Questions of Survival, Social Structure and Ecological Environment' (1992a) 9 *Theory, Culture and Society* 97-123 at page 102; and Giddens, A. (1991) at pages 124-125. Jonas also

acknowledges that the modern era presents technological hazards that defy the 'nearness and contemporaneity' of traditional society, Jonas, H. (1979) at page 7.

³² Beck, U. (1994) at page 8.

³³ Goldblatt, D. (1996) at page 159.

³⁴ Beck, U. (1992) at page 22.

³⁵ Beck, U. (1995) at page 126.

accident? This is why the question of 'How many people died from the accident at Chernobyl?' is still statistically undecidable in principle. The arguments that rage over it are like battles between phantom armies."³⁶

Our exposure to physically imperceptible and incalculable hazards makes them perceptible only through individual experience. Post-industrial risks only exist to the extent that they are perceived.³⁷ Risk in the modern era, therefore, is a social construct. Unlike industrial hazards, which Beck claims can objectively exist independently of perception, the concept of socially constructed risk paves the way for diverse pluralism in expert opinion.³⁸ As a result, experts cease to adopt a united front and are no longer seen as being in a position to determine what constitutes a risk. The concept of 'expertise' becomes more synonymous with *un*certainty than with certainty. Beck refers to the undercutting of expert authority in the aftermath of Chernobyl:-

"We felt like we were hanging from the marionette strings of these experts and institutions who continually contradicted each other. They kept saying they had everything well in hand, and it constantly turned out not to be true. To get answers to the most everyday questions, like 'Can I let my kid play in the sandbox? Can I buy mushrooms? Are all the vegetables poison, or just those from specific regions?' we were dependent on the minute to minute statements of experts who were simply blinding in their contradictions. And underneath it all was the horrifying thought that maybe food itself might now be poison."³⁹

By virtue of scientific and technological progress, local risks metamorphose into *systematic* risk.⁴⁰ Endorsing Keynes' argument that systematic risk is radically uncertain, Beck claims that the industrial model of quantification is rendered ineffective, and that society in the new era is confronted with insurmountable

³⁶ Beck, U. and Willms, J. (2003) at page 115.

³⁷ Beck, U. (1995) at page 12.

³⁸ Giddens refers to this as the 'grand narrative' being replaced by heterogeneous claims to knowledge. Giddens, A. (1991) at page 2.

³⁹ Beck, U. and Willms, J.(2003) at page 117.

⁴⁰ *Ibid.* at page 127.

threats.⁴¹ Yet despite the portrayed gravity of the risks threatening society, Beck maintains that risks in the post-industrial risk era are not taken seriously⁴² – which is confirmed by the continuing tendency to equate risks with probabilities. He notes that:-

"[w]e still seem unable to accept the crucial difference between probability and radical uncertainty, and to come to terms with the fact that the latter now dominates, at least among the risks that occupy the public stage. This basic misunderstanding permeates even the mindset of the natural sciences."⁴³

This ignorance is reflected by the tendency of decision-making institutions to overlook the inherent uncertainty of risk⁴⁴ by denying any danger that cannot be expressed and 'controlled' by way of statistics. Beck points out that:-

"[w]hen the affected and worried people take their case to the scientists, they find themselves talking to a group whose most identity-defining belief is that the canons of causal evidence and inference must always be strictly adhered to. When these criteria can't be satisfied, scientists can be depended upon to explain away any new risk as mere fantasy without giving it further consideration."⁴⁵

Ironically, the smokescreen of controllability created by quantification only serves to heighten the paranoia and anxiety felt when a global risk crisis occurs and we realise that, despite our calculations, we are still oblivious to the nature of that risk and the way in which to deal with it.⁴⁶ And furthermore, despite this institutional denial, incalculable risks still seep into those institutions and actively destabilise them. The

⁴² Beck, U. and Willms, J.(2003) at page 116.

⁴¹ Keynes, J. M. A Treatise on Probability (Macmillan; London; 1921) in The Collected Writings of John Maynard Keynes: Volume. VIII (Macmillan; London; 1973). See Keykhah, M. 'The Shape of Uncertainty: Implications for Decision Making' (Economic Geography Research Group; University of Oxford; Oxford; 2002) Working Papers, WPG 02-03, at page 4.

⁴³ Ibid.

⁴⁴ *Ibid.* at page 117.

⁴⁵ *Ibid.* at page 120.

⁴⁶ *Ibid.* at page 116.

goal is to be free from risk, however, risk *aversion* necessarily leads to risk *procreation*. Beck explains that:-

"[e]veryone tries to free themselves from risk, but it continues to multiply and permeate. It's as if we've knocked over a honeypot, and in our efforts to rub it off, we succeed only in getting honey stuck to every part of the social body. It's a self-negating process, in which everything society's institutions do to free themselves only spreads the risk and helps to dissolve their legitimacy."⁴⁷

Underlying Beck's 'honeypot analogy' is a process referred to as *reflexive modernisation* – which is central to the transition from industrial to risk society. The following section introduces reflexive modernisation, and highlights that the emergence of new, global, systematic hazards specifically in risk society is by no means a coincidence. The proliferation of risk in post-industrial society is the direct result of the reflexive modernisation of social structures. The reflexive phase is distinguished by the dissolution of the 'grand narrative' model which confers upon social systems a definitive past and a predictable future.⁴⁸

8.2 Reflexive modernisation

Modernisation in the post-industrial era manifests itself in technological and scientific progress which acts upon itself. It is self-destructive, dissolving the foundations upon which traditional society is based. The self-destruction of society is inextricably linked to a process known as *reflexive modernisation*.⁴⁹ It is worth noting from the outset that *reflexive* modernisation is distinct from the process of modernisation. Beck explains that whilst *simple* modernisation involves the disembedding of traditional social structures and subsequent re-embedding of industrial social structures, *reflexive* modernisation entails the disembedding industrial social

⁴⁷ *Ibid*. at page 122.

⁴⁸ Giddens, A. (1991) at page 2.

⁴⁹ Beck, U. (1994) at page 2. Jonas also makes a similar reference, describing the technological era as 'cumulatively self-propagating', Jonas, H. (1979) at page 7.

structures and subsequent re-embedding of a *new* stage of modernity.⁵⁰ Simple modernization is characterised by a sense of utopic evolution, involving, for example, the development of means of production, structural differentiation or functional integration. Reflexive modernisation, however, marking the passage from industrial to risk society, is a much *darker* process.⁵¹ It describes a condition in which modernity confronts itself, forcing "a radicalization of modernity, which breaks up the premises and contours of industrial society and opens paths to another modernity."⁵² Accordingly, modernization begins to take on itself as an object of reflection. Modernity begins to modernize its own foundations, destroying itself and creating a new social order. To that end, modernisation is its own gravedigger – it has become "a theme and a problem for itself."⁵³

Although reflexive modernisation has its roots fixed in the critique of scientific knowledge, it is applicable throughout society. For Beck, the term 'risk society' signifies a condition in which social, economic, political and cultural systems are confronted with self-generated uncertainty, which in turn plants increased complexity, contingency and disintegration at the heart of those systems. Following on from this, risk is defined as "a systematic way of dealing with hazards and insecurities induced and introduced by modernization itself."⁵⁴

Crucially for Beck, reflexive modernisation changes the societal role assigned to science and knowledge, setting it apart from simple modernisation. Whereas in industrial society, science, rationality and expertise were looked upon as key determinants of the definition and management of risk, science in risk society has a dual role. On the one hand, scientific progress in the reflexive phase has generated a new-fangled set of risks and hazards, thus undermining ontological security. On the other, science is an indispensable tool for the comprehension and measurement of such risks. As Beck notes. "[s]cience is *one of the causes, the medium of definition and the source of solutions to risks*".⁵⁵ This interplay between the functions of science in risk society has meant that scientific progress is a contradictory process.

- ⁵² Beck, U. (1994) at pages 8-9.
- ⁵³ *Ibid.* at page 8.
- ⁵⁴ Beck, U. (1992) at page 21.
- ⁵⁵ Ibid. at page 155.

⁵⁰ Ibid.

⁵¹ Beck, U. (1995) at page 2.

The growth of scientific success has created negative by-products, in the form of risks, which themselves become subject to scientific analysis. By virtue of a system of checks and balances being placed within the process of modernization itself.⁵⁶ scientific knowledge is critically evaluated and reshaped. The medium of selfconfrontation is, unsurprisingly, an impetus for change. In other words:-

"The expansion of science presupposes and conducts a critique of science and the existing practice of experts in a period when science concentrates on science, and therefore scientific civilization is subjecting itself to a publicly transmitted criticism that shakes its foundations and its own selfconception."57

The upshot of this paradoxical relationship between science and risk is an inherent public scepticism of science, and the demonopolization of scientific claims of its ability to solve the problems introduced by risk society.⁵⁸ Beck calls this science's "loss of function."⁵⁹ Jonas makes a similar observation that heightened technological progress creates a disparity between the scientific capacity to produce the future and the scientific capacity to know the future implications of scientific progress.⁶⁰ This juxtaposition is described as:-

"[t]he gap between the ability to foretell and the power to act creates a novel moral problem."⁶¹

Ironically, the negative effects of scientific progress, together with growing awareness of the limits of scientific foresight, has been offset by increasing demand for scientific assurances of safety.

⁵⁶ Jaeger, C. C. et al, Risk, Uncertainty, and Rational Action (Earthscan; London; 2001) at page 210.

⁵⁷ Beck, U. (1992) at page 156.

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ This argument appeared in a paper delivered by Professor Barbara Adam titled 'Minding Futures: An Exploration of Responsibility for Long Term Futures' at the 'Sensing the Unsensed' workshop, Lancaster University, October 2004. Paper posted on website: http://www.cf.ac.uk/socsi/futures/mindingfutures.pdf, accessed December 2004.

Ibid. at page 8.

"The further scientization proceeds and the more clearly risk situations and conflicts enter public conscience, the greater becomes the pressure to act, and the more techno-scientific society threatens to metamorphose into a scientifically produced 'taboo society'."⁶²

This circular relationship means that the production of risk is the direct consequence of scientific efforts to minimise insecurity.⁶³ This is what Beck is referring to when he uses the term 'manufactured uncertainty.'⁶⁴ Beck comments on the systematic generation of uncertainty:-

"What we are finding now is that the world isn't quite as the Enlightenment thinkers assumed. Increasing our knowledge about the world ... create[s] new forms of risk for which we have little prior experience – and which can't be calculated on the basis of established time-series, for the data don't exist ... What I call 'manufactured uncertainty' is bound up more with the advance of knowledge than with its limitations. The economist Frank Knight made the distinction between risk and uncertainty. He argued that risk concerns future probabilities which can be calculated, uncertainty, ones that cannot. But that distinction doesn't hold water: there are too many fuzzy areas in the middle."

Although here, Beck claims that manufactured uncertainty is related to knowledge rather than a lack of it, in later works he introduces the notion that manufactured uncertainty has a double reference.⁶⁶ Manufactured uncertainty can be the product of knowledge *and* unawareness. They are interrelated. Scientific progress necessarily implies a greater accumulation of knowledge, which in turn provides new sources of uncertainty. New knowledge can turn normality into risk overnight.⁶⁷ Beck comments that "[b]y opening more and more new spheres of action, science creates

⁶² *Ibid.* at page 157.

⁶³ Beck, U. (1995) at page 12.

⁶⁴ Beck, U. (1999) at pages 5, 6, 111-112, 140-142.

⁶⁵ Giddens, A. and Pierson, C. Conversations with Anthony Giddens: Making Sense of Modernity (Cambridge; Polity Press; 1998) at pages 104-5.

⁶⁶ Beck, U. (1999) at page 140.

⁶⁷ Ibid. at page 58.

new types of risk as well."⁶⁸ However, the opposite is also true. Scientific progression can also work to highlight unawareness and the inability to know. For Beck, the inability to know is related to the concept of 'highly developed expert rationality'⁶⁹ – which is ultimately the product of scientific advancement. The reflexive phase marks a departure from linear forms of knowledge in which closed circles of experts act upon knowledge in a consensual manner. Instead, non-linear forms of knowledge develop as a result of hyper-complexity revealed by scientific development, producing a situation in which knowledge systems are no longer closed and consensual. By stark contrast, non-linear forms are open and pluralistic, inviting a mixture of rationales to the forum, and generating uncertainty and dissent. This pluralism undermines the ability of closed scientific system to unanimously act upon knowledge, and thus calls for the opening up of science to outside knowledge. The transition to the reflexive phase occurs when the inquiry into our inability to know induces a shift of focus towards external rationalities. This dissolves the foundations of mono-rationality underlying the structure of industrial society.

The association of uncertainty with non-linear forms of knowledge calls to attention the central theme to Beck's concept of reflexive modernisation. The existence of uncertainty in relation to risk ultimately means that, in effect, no one is an expert and yet at the same time *everyone* is an expert.⁷⁰ Thus, control over decision-making in the face of uncertainty should be wrested from scientific experts and granted all members of society. Determining the course of action in the face of uncertainty is no longer something that can be legitimately done by scientific experts, not only because science creates as much uncertainty as it dispels, but also because expert-systems cannot maintain public trust typically enjoyed in industrial society. Reflexivity, therefore, derives from the self-refutation and distrust of the rational-calculative model of scientific expertise.

It is interesting to draw comparison between Beck's concept of reflexive modernisation and the theory of scientific displacement advocated by the likes of

⁶⁸ *Ibid*. at page 140.

⁶⁹ *Ibid.* at page 141.

⁷⁰ Beck, U. (1994) at pages 5-13; Smith, R. J. 'Sustainability and the Rationalisation of the Environment' (1996) 5(1) Environmental Politics 25-47, and Cohen, M. J. (ed) Risk in the Modern Age: Social Theory, Science and Environmental Decision-Making (Macmillan; London; 1999).

Thomas Kuhn and Karl Popper. Models of scientific displacement serve to emphasise Beck's contention that science generates uncertainty – scientific problems are not conclusively solved, but are superseded by new and more pressing problems.⁷¹ As technology becomes more complex, so we are confronted with more risk, and the more technology autopoietically develops in order to control heightened risk, the more risk autopoietically procreates.⁷² Scientific advancement is necessary in order to avoid risk, but increased scientific inquiry generates further risk. In the words of Luhmann, "[s]cientific analysis does not serve to solve problems but to multiply them."⁷³ The very essence of scientific displacement is centred on the notion that scientific orthodoxies are pursued to such a degree that they "take a pratfall and have to be replaced."⁷⁴

8.3 Models of scientific displacement

Traditionally, scientific progress has been seen as a *cumulative* process of uncovering the truth. Underlying this notion is the theory of scientific realism – that the objects of scientific knowledge exist independently of the knowledge of them; that the truth can be objectively observed; and that scientific discovery will form a permanent part of knowledge. However, the works of Karl Popper and Thomas Kuhn offer alternative models of scientific progress that dispel the notion that scientific knowledge develops in a cumulative and enduring manner. Instead, they propose models of scientific displacement. Accordingly, scientific progress is revolutionary. As knowledge is created, gaps of ignorance are filled. However, rather than

⁷¹ This point has been endorsed by Giddens: "[e]ven philosophers who most staunchly defend the claims of science to certitude, such as Karl Popper, acknowledge that, as he expresses it, 'all science rests upon shifting sand.' In science, *nothing* is certain, and nothing can be proved, even if scientific endeavour provides us with the most dependable information about the world to which we can aspire. In the heart of the world of hard science, modernity floats free." Giddens, A. (1991) at page 39.

⁷² For a detailed analysis of the concept of autopoiesis, see Maturana, H. and Varela, F. Autopoiesis and Cognition: The Realization of the Living (Reidel Publishing; Dordecht, Holland; 1972); Philippopoulos-Mihalopoulos, A. 'The Silence of the Sirens – Environmental Risk and the Precautionary Principle' (1999) 10(2) Law and Critique 175-197, at page 177; Nelken, D. 'Changing Paradigms in the Sociology of Law', in Teubner, G. (ed) Autopoietic Law: A New Approach to Law and Society (Walter de Gruyter; Berlin; 1988) 191-216, at pages 196 and 199, where the author describes autopoiesis as a system that displays characteristics of circularity, self-observation, awareness of its own autonomy, operation according to its own code, and a focus on its correspondence to itself.

⁷³ Luhmann, N. Ecological Communication (Polity Press; Cambridge; 1989) at page 78.

⁷⁴ Lowrance, W. W. 'The Nature of Risk', in Schwing, R. C. and Albers, W. A. (eds) Societal Risk Assessment – How Safe is Safe Enough? (Plenum Press; New York; 1980) at page 7.

advancing along the path to scientific truth, the generation of knowledge, as well as resolving one scientific quandary, simultaneously produces another knowledge gap. New scientific knowledge replaces old, and at the same time unearths a new set of questions. McMullin explains that as more scientific puzzles are solved, scientists are not led closer to the truth, because there is no scientific truth.⁷⁵ Instead of reaching a new level of understanding, scientists reach a new illusion of understanding.

The works of Popper and Kuhn are renowned for questioning the traditional view of scientific history as a process by which scientists add new pieces to the everexpanding scientific puzzle. Of the two, Popper's analysis of scientific progress in Conjectures and Refutations – The Growth of Scientific Knowledge offers the more explicit model of scientific displacement. He argues that scientific process begins with a problem. Knowledge starts with a problem and ends with a problem. In order to solve a scientific problem, an 'anticipation',⁷⁶ or hypothesis is proposed which is subsequently subjected to a four stage testing procedure exercising deductive logic:first, its internal consistency is tested;⁷⁷ secondly, its logical form is tested so as to determine whether it has the character of scientific theory;⁷⁸ thirdly, it is compared with other theories so as to determine whether it will advance scientific knowledge;⁷⁹ and finally, its conclusions are empirically applied and observed.⁸⁰ Irrespective of the number of instances in which a hypothesis is confirmed, it only takes a single conflicting observation to falsify it. In the event of falsification, the hypothesis is refuted, and with the aid of 'imaginative thinking', a new conjecture if proposed. Popper concedes that "every discovery contains 'an irrational element', or 'a creative intuition'."81

The knowledge process works on the basis that science is about progressing from one problem to the next. The most lasting contribution to the advance of scientific

⁷⁵ McMullin, E. 'The Shaping of Scientific Rationality', in McMullin, E. (ed) Construction and Constraint: The Shaping of Scientific Rationality (University of Notre Dame Press; Notre Dame; 1988) at page 38.

Popper, K. R. Conjectures and Refutations - The Growth of Scientific Knowledge (Routledge; London; 1963) at page 32.

Ibid.

⁷⁸ Ibid.

⁷⁹ Ibid. at 33. ⁸⁰ Ibid.

⁸¹ Popper, K. R. The Logic of Discovery (Hutchinson; London; 1968) at page 32.

knowledge that a theory can make, Popper argues, is the new problems it creates through the course of rigorous testing, falsification, refutation and discovery.⁸² In this way, science can help to progress towards the truth, but we will never be certain that we have the final explanation.

Kuhn rejects the notion that science grows steadily as observations accumulate. Instead explains the acquisition of knowledge in terms of periodic revolutions – or changing 'paradigms'. A paradigm is an accepted example of actual scientific practice providing a model of particular coherent traditions of scientific research.⁸³ Scientific research necessarily takes place within a paradigm since the random exploration of the world would present a complex and mammoth task. Research is thus constrained by the scientific assumptions and methodology advocated by the dominating paradigm. The paradigm restricts the questions a scientist can legitimately ask, and it confines the answers to the product of approved scientific technique. During 'normal science', as Kuhn calls it, relatively esoteric problems present themselves forcing scientists to investigate the paradigmatic claims in 'unimaginable' detail.⁸⁴ This is what Beck is referring to when he states that:-

"[s]triding forth along the path of specialization, it does not, cannot stop at the deconsecration of its own foundations and products. Anyone who lets his doubts gnaw at his own fundamental principles can, if he does the job well, realize that he has none."⁸⁵

Beck goes on to note that:-

"[p]eople who inquire further, learn more, and also more about the fragility and limitations of their own fundamental principles and statements; and therefore they learn less."⁸⁶

⁸² Popper, K. R. (1963) at page 222.

⁸³ Kuhn, T. The Structure of Scientific Revolutions (University of Chicago Press; Chicago; 1962) at page 10.

⁸⁴ *Ibid.* at page 24.

⁸⁵ Beck, U. (1995) at page 68.

⁸⁶ *Ibid.* at page 121.

The inevitable discovery of some uncertainty or anomaly forces the scientist to adopt a different attitude to the paradigm, and undertake more meticulous research. Kuhn describes the increasing rigour with which scientific inquiry is conducted as a transition from *normal* to *extraordinary* research.⁸⁷ More comprehensive and thorough investigation draws to attention the weaknesses of a current paradigm and generates the momentum for change. Scientific revolutions "are inaugurated by a growing sense ... that an existing paradigm has ceased to function adequately in the exploration of an aspect of nature to which that paradigm itself had led the way."⁸⁸ In response to this, scientists propose alternate paradigms, adopting new instruments and looking in new places for answers. Gradually, one of the alternate paradigms will triumph over competing paradigms. As the scientific community converts itself to the new paradigm, scientific research commences under a new set of basic assumptions and scientists reinterpret old data in new ways. Kuhn described the process of the evolution of a new paradigm:-

"At the start a new candidate for paradigm may have few supporters, and on occasions the supporters' motives may be suspect. Nevertheless, if they are competent, they will improve it, explore its possibilities, and show what it would be like to belong to the community guided by it. And as that goes on, if the paradigm is one destined to win its fight, the number and strength of the persuasive arguments in its favour will increase. More scientists will then be converted, and the exploration of the new paradigm will go on. Gradually the number of experiments, instruments, articles, and books based upon the paradigm will multiply. Still more men, convinced of the new view's fruitfulness, will adopt the new mode of practicing normal science, until at last only a few elderly hold-outs remain."⁸⁹

Unlike the traditional view that scientific progress in cumulative, Kuhn's model proposes that new knowledge replaces older, incompatible knowledge. From this

⁸⁷ Kuhn, T. (1962) at page 91.

⁸⁸ *Ibid.* at page 92.

⁸⁹ Kuhn, T. (1962) at page 159.

perspective, scientific progress is presented are being revolutionary, invoking fundamental changes in method and understanding, rather than cumulative.

Arguably, the works of Popper and Kuhn can be reconciled with Beck's notion of reflexive modernity on the grounds that the transition to modernity has led to an acceleration of the process of scientific displacement. Whereas, conceivably, both Popper and Kuhn envisaged scientific displacement occurring over a relatively lengthy period, Beck's notion of reflexive modernisation induces the process of scientific displacement over a much shorter timeframe. Eloquently demonstrating the position, Beck states that:-

"[o]n the one hand, technologists claim that their declarations about risks are strictly scientific, including the maximum permissible levels on which they depend. The observer rubs his eyes in disbelief at the miraculous power of the engineering sciences; these have now managed to overcome the gravity of the insight that no force in the universe, no matter how sparkling its formulae, can yield normative propositions concerning risk acceptance. Yet no sooner has one accustomed oneself to this feat of magic than one has to acknowledge that the technologists have done more, hanging the norms they claim to prescribe from the gallows of fluctuating maximum possible levels. Now the technologists' claims to accuracy dangle, one beside another, from the ropes of the maximum permissible levels they have tied around their own necks."⁹⁰

8.4 Reflexive modernisation and individualisation

Directly relating to reflexive modernisation is the process of individualization.⁹¹ In fact, individualization is the driving force of a reflexively modern phase. It has been described as "socially most astonishing, most surprising and perhaps least understood

⁹⁰ Beck, U. (1995) at page 114.

⁹¹ Lash, S. 'Reflexivity and its Doubles: Structure. Aesthetics, Community', in Beck, U. et al (1994) chapter 3 at page 114.

phenomenon of the last twenty years",⁹² and involves an "unexpected renaissance of an 'enormous subjectivity' – inside and outside institutions."⁹³ According to Lash, the process of individualisation is the motor of social change.⁹⁴ Although Beck himself admits that *Risk Society* focused primarily on the risk thesis rather than individualisation,⁹⁵ his later publications work to redress this imbalance.⁹⁶ Accordingly, individualisation underlies the dissolution of traditional social structures characteristic of industrial society. Thus, individualisation provides the means through which a reflexive state is achieved. It is perhaps surprising, therefore, that Beck initially played down its significance in his theory of modernity.

Nevertheless, it has since become obvious that the process of individualisation operates at a profound level in Beck's account of the transition from industrial to risk society. Given its significance, it is fitting to go beyond paying it mere lip-service. The purpose of this section is to introduce Beck's concept of individualisation, and to place it in the context of reflexive modernisation.

From the outset, Beck is keen to establish the proper meaning of individualisation. He states:-

"Let us be clear what 'individualization' means. It does *not* mean individualism. It does *not* mean individuation – how to become a unique person. It is *not* Thatcherism, not market individualism, not atomization."⁹⁷

In fact, it is quite the opposite. Whereas market individualism is founded on the notion of predictive economic rationality, individualism as it is envisaged by Beck is rooted in the politics of the free market. This is not a new concept. Individualisation has occurred throughout history in phases of revolution – during, for example, the

⁹² Beck, U. (1999) at page 68.

⁹³ Ibid.

⁹⁴ Lash, S. (1994) at page 114.

⁹⁵ Beck, U. and Beck-Gernsheim, E. *Individualization* (Sage; London; 2002) at page xxi; see also Lash, S. 'Foreword: Individualization in a Non-Linear Mode', in Beck, U. and Beck-Gernsheim, E. (2002) vii-xiii, at page vii where Lash notes that "[t]he individualization thesis, for its part, has passed virtually ignored."

⁹⁶ See, for example, Beck, U. and Beck-Gernsheim, E. (2002); Beck, U. and Willms, J. (2003).

⁹⁷ Beck, U. (1999) at page 9.

Renaissance; and the emancipation of peasants from feudal repression⁹⁸ – when individuals have been freed from traditionally prescribed roles. From this perspective, individualisation is a term coined by Beck to describe the liberation of individuals from constraints imposed by social institutions and the creation of new forms of social identity. This freedom from the collective forms the basis upon which Beck's theory of modernity and the transition to risk society is established.

However, Beck is careful to highlight that individualisation in risk society differs in one crucial respect from individualisation in earlier historical phases. The difference, although subtle, is critical to an understanding of his thesis. In order to illustrate the position, it is worth noting Beck's definition of individualisation in the reflexive phase. Before doing so, it is important to observe that Beck's later works adopt the terminology 'first/second modernity' in place of 'industrial/risk society'. Thus, in the following extract, the phrase 'second modernity' denotes 'risk society':-

"[W]hat individualization means in this constellation is disembedding without re-embedding. In the second modernity, the individual becomes, for the first time in history, the basic unit of social reproduction."99

In other words, individualisation as a component of reflexive modernisation brings about the liberation of the individual from social structures (disembedding) without the formation of new social structures (re-embedding) through which the individual By contrast, individualisation in previous phases is establishes his identity. characterised by the disembedding and subsequent re-embedding of social control structures. Thus, until the second modernity (or risk society), individualisation has always been offset by the re-empowerment of social structures. Conversely, the process of individualisation leading to the second modernity destructs social structures and the individual assumes central place. According to Beck, this is evident in three ways.¹⁰⁰ First, social classes based on status are dissolved. Secondly, women are freed from the traditional role of dependent house-wife. However, this 'detraditionalization' does more than simply redress rigid gender roles - Beck notes

 ⁹⁸ Beck, U. and Beck-Gernsheim, E. (2002) at page 202.
 ⁹⁹ Beck, U. and Willms, J. (2003) at page 63.

¹⁰⁰ Beck, U. and Beck-Gernsheim, E. (2002) at pages 202-203.

that "[t]he entire structure of family ties has come under pressure from individualization and a new negotiated provisional family composed of multiple relationships – a 'post-family' – is emerging."¹⁰¹ Thirdly, the rigidity of old forms of work routine is being replaced by new flexible working hours and options to conduct business from the home.

Thus, rather than being a concept relating to the individual, individualisation is a *structural* concept, meaning the dissolution of, and disenchantment with, collective foundations of industrial society.¹⁰² Individuals are 'released' from industrial society into 'the turbulence' of risk society.¹⁰³ Accordingly, individualisation undercuts structures of class, occupation, sex roles, the nuclear family, trade unions, and the welfare state leaving individuals to master the notion of risk without being able to make decisions on an established institutionalised basis.¹⁰⁴ Thus, individualisation removes any sense of consensus, certainty and security, traditionally associated with the industrial phase.

The position can be summarised as follows. Individualisation is a process by which society's institutions, and more specifically, the relationship of the individual to them, are transformed. Individual action must be seen as being independent of collective pressures,¹⁰⁵ and individual nonconformity subverts social orthodoxy.¹⁰⁶ The upshot is the establishment of a more indeterminate coexistence. Rigid, pre-determined 'biographies'¹⁰⁷ are replaced by a 'dialogic existence'.¹⁰⁸ In other words, Beck claims that the resolution of conflict between individuals can no longer be achieved by reference to pre-given trajectories. Instead, he argues that "the pre-given intermeshing of role-sets is replaced by a much more fluid situation wherein nothing is pre-given and everything has to be negotiated."¹⁰⁹ The only way in which the extreme complexity and indeterminacy of risk society can be dealt with is through a

¹⁰¹ *Ibid.* at page 203.

¹⁰² Beck, U. (1999) at page 74.

¹⁰³ Ibid. at page 75.

¹⁰⁴ Beck, U. (1994) at page 8.

¹⁰⁵ Beck, U. and Willms, J. (2003) at page 65.

¹⁰⁶ *Ibid*. at page 68.

¹⁰⁷ Beck, U. and Willms, J. (2003) at page 65.

¹⁰⁸ *Ibid.* at page 69.

¹⁰⁹ Ibid. at page 65.

continuous process of translation between individuals. The collective no longer plays a meaningful part.¹¹⁰

In relation to risk, this process results in individuals being increasingly forced to bear unforeseeable consequences of the decisions they have made. The supremacy of the individual over the collective means that there is a distinct loss of the institutional underpinning of decision-making, and cultural definitions are "are set in a flux".¹¹¹ This is particularly well demonstrated by the struggle over risk definitions, which in turn reinforces the argument that the hyper-complexity of the individualised phase dissolves the legitimacy of any claims to certainty. Douglas explains that:-

"[n]o one gives us certainty, even in science. When we lived in [an industrial] culture, we used to think that either a thing was known to be true or it was wrong; a fact was a fact, and as such it guaranteed deductions made from it. Now that we are committed to an individualist culture, the competition is on; knowledge has to be defended at every point; the open society guarantees nothing."112

Thus, the process of individualisation is central to reflexive modernisation since it sets the scene for ambiguity and uncontrollability. The breakdown of societal institutions makes it possible for individual risks to escape the collective monitoring and protection facilities of industrial society. The failure of such institutions to exercise control of threats not only encourages self-criticism, but also increases the demand on institutions to define and manage those threats. This schizophrenia raises interesting questions in relation to the operation of precaution.

¹¹⁰ *Ibid.* at page 69. ¹¹¹ *Ibid.* at page 128.

¹¹² Douglas, M. 'Risk as a Forensic Resource', in Burger, E. J. (ed) Risk (University of Michigan Press; Michigan; 1993) pages 1-16, at page 11.

8.5 Implications for precaution

Although sociological literature is frequently cited in analyses of risk, its implications for the precautionary principle are seldom explored.¹¹³ The overriding conclusion to draw is that the relationship between risk assessment and precaution is beset by fundamental issues arising in relation to the role of science in regulation. Despite the fact that this risk literature reflects the finding of social constructivism that risk is a 'multi-level game' that cannot be reduced to a merely technical question,¹¹⁴ it brings to the forum profound questions about the relationship between precaution, scientific expertise, and risk assessment.

As Part One of this thesis has illustrated, a significant consequence of the definitional deficit of precaution is the ambiguity relating to its point of application. The question is: when do we enter into precautionary-territory? When does the precautionary principle, as opposed to the principle of prevention, apply? As Part One of this thesis illustrates, this issue has been the focus of a number of recent judgments passed down by the European Courts and the WTO Appellate Body. Part Three continues with this theme, demonstrating through a case-study of the BSE crisis that complete reliance on scientific risk assessment creates a tendency to overestimate control over potential hazards. The result is the constrained use of precaution.

Sociological risk literature is useful in that it provides substance to the argument that the operation of precaution induces a consideration of deep-rooted interactions between the formal discourse of science and the future. A consideration of these sociological theories leads to the abstract conclusion that "we simply cannot know the future (or it would not be the future)".¹¹⁵ With this in mind, a precautionary response to suspected threats can be seen as a valid attempt to circumvent unwanted consequences. In the context of this sociological underpinning, the notion of precaution might be understood as embodying the realisation that "no one is in a

¹¹³ Jenny Steele published a book in 2004 called *Risks and Legal Theory*. Although she presents risk regulation in the context of sociological theory (see, for example, pages 44-5), she pays relatively little attention to its relationship with the precautionary principle (pages 196-9). Steele, J. *Risks and Legal Theory* (Hart; Oxford; 2004).

¹¹⁴ Beck, U. and Willms, J. (2003) at page 129.

¹¹⁵ Luhmann, N. (1993) at page 48.

position to claim knowledge of the future or the capacity to change it."¹¹⁶ This undermines the premise upon which risk assessment is based – that, in order to measure risk, it is necessary to project the past into the future.¹¹⁷

The underlying problem, it would appear, is that quantitative risk assessment does not distinguish between *potential* and *actual* risks.¹¹⁸ It assumes that the frequency and magnitude of future risks will reflect those that have already been observed.¹¹⁹ Thus, on a conceptual level there is a conflict between risk assessment and the precautionary principle – primarily because the precautionary principle is only intended to deal with *potential* hazards. The definition of the precautionary principle contained in Principle 15 of the Rio Declaration confines its application to situations in which there are 'threats of serious or irreversible damage'. It is essential to note the use of the word 'threat', which implies that the operation of the precautionary principle is confined to *prospective* hazards.

As it stands, there exists a tension between the operation of precaution and the materialisation of the 'trans-scientific' state.¹²⁰ A problem arises when the implementation of the precautionary principle is determined by scientific means. When scientific risk assessment is relied upon to clarify and communicate uncertainty, the results appear to be more certain, or less value-laden, than is defensible.¹²¹ The scientific construction of potential hazards, therefore, can preclude a precautionary response when it is, in fact, appropriate. This has led Giddens to conclude that risk assessment has itself become 'inherently risky'¹²² and of 'imponderable character'.¹²³ Notions of predictability based upon extrapolations of

¹¹⁶ Ibid.

¹¹⁷ *Ibid.* at page 43.

¹¹⁸ Silbergeld, E. K. (1993) at page 75.

¹¹⁹ Keykhah, M. 'The Shape of Uncertainty: Implications for Decision Making' (Economic Geography Research Group; University of Oxford; Oxford; 2002) *Working Papers, WPG 02-03*, at page 4.

¹²⁰ Weinberg, A. M. 'Science and Trans-science' (1972) 10 *Minerva* 209-222, at page 209. Weinberg describes questions "which can be asked by science and yet which *cannot be answered by science*."

¹²¹ I would like to express thanks to Anne Ingeborg Myhr (Institute of Genomics, Tromsø) for her valuable comments. Reference is made here to her thesis submitted in partial fulfilment of a Doctor Scientarium degree: Myhr, A. I. 'Precaution, Context and Sustainability' (2002) Department of Microbiology and Virology, Institute of Medical Biology, Tromsø, Norway, at page 15.

¹²² Giddens, A. (1991a) at page 122.

¹²³ *Ibid*. at page 124.

the past have been undermined by their inability to secure a calculable future.¹²⁴ Consequently:-

"When we seek definitions of the concept of risk, we immediately find ourselves befogged, with an impression of being unable to see beyond our own front bumper."125

This chapter ends, therefore, with the recognition that the notion of precaution is consistent with recognition of the complexity of ecological hazards, lack of scientific understanding, and high decision stakes. It challenges the authority of science in policy decision-making, and suggests that an alternative approach to the future is desirable. Yet, if this is juxtaposed with the fact that the operation of precaution is reliant on reductionist techniques of risk assessment, it is conceivable that its scope of application is jeopardised. The following chapter continues to draw on Beck's thesis to illustrate that the assumption that reductionism eliminates uncertainty and complexity¹²⁶ conflicts with the broad notion of anticipatory conduct – which, of course, encompasses precaution.

 ¹²⁴ Adam, B. and Van Loon, J. (2000) at page 6.
 ¹²⁵ Luhmann, N. (1993) at page 6.

¹²⁶ Myhr, A. I. (2002) at page 12.

Chapter Nine

The relativity of risk and the ability of the precautionary principle to <u>establish an 'ethics for the future': a critical analysis</u>

9.0 Introduction

Chapter Seven provides a theoretical basis for this chapter. It introduced the supremacy of scientific expertise using a temporal distinction between industrial and post-industrial societies. It presented the philosophical rational for the combination of the limited ability of conventional risk assessment models to predict the future and increasing angst about exercising control over the unknown. This chapter considers the operation of precaution in Beck's risk society, and, armed with an understanding that scientific parochialism does not always engender ontological security, it shows that the practice of resigning the application of precaution to a statistical interpretation of the future conceptually limits its application.

The phrase 'ethics for the future' is taken from Hans Jonas' analysis of environmental hazards in contemporary society.¹ In my opinion, Jonas' work in this field is underrated. Risk literature tends to focus solely on the writings of Beck, Giddens and Luhmann, without citing Jonas' thesis which captures the inadequacies of scientific dialogues with the future. This chapter seeks to remedy this oversight.

9.1 Beck's thesis and the precautionary principle

Academics agree that the emergence of the precautionary principle is a direct response to concern over *new* dangers threatening modernity. De Sadeleer, for example, notes that:-

¹ Jonas, H. The Imperative of Responsibility: In Search of an Ethics for the Technological Age (University of Chicago Press; Chicago; 1979).

"[t]he emergence of the precautionary principle can be traced from disenchantment with classical scientific culture, which, convinced with the linear nature of the universe, as predictable as the path of a cannon ball, could find a remedy for any problem. Scientific predictability comes up against staggering limits in the field of the environment Contemporary science cannot deliver certainty; as at the end of the day, it throws up more questions than it solves."²

It is clear that the precautionary principle is a by-product of conditions specific to the modern risk era. Not only has it emerged out of exposure to environmental catastrophes, but also out of the realisation that our knowledge of the future is limited. It can be said that the precautionary principle has transpired as a result of a desire to have control over the uncontrollable future. It has spawned from a deeply-embedded confidence in the human ability to manage and manipulate impending dangers, which derives from traditionally-scientific approaches to prediction. Yet it also reflects an understanding of the limits of the ability of scientific method to determine and make safe potential hazards. I will call this 'the paradox of precaution'.³

It is useful here to recall Beck's temporal distinction. Whereas traditional industrial society is underpinned by a compelling faith in science to predict and control future hazards, risk society is marked by a desire to extend control of the future coupled with an awareness of the inability of existing scientific knowledge to predict prospective dangers. Crucially, it is the fear of the unknown, which is notably absent in the industrial phase, that has prompted the development of the precautionary principle. Yet, according to Beck's thesis, the conditions in which fear and anxiety are entrenched, whilst giving rise to the demand for anticipatory action, render unfeasible 'current action' in the face of future hazards. The precautionary principle intended to apply *before* the materialisation of uncertain environmental hazards. It therefore falls

² De Sadeleer, N. 'The Effect of Uncertainty on the Threshold Levels to which the Precautionary Principle Appears to be Subject', in Sheridan, M. and Lavrysen, L. (eds) *Environmental Law Principles in Practice* (Bruylant; Bruxelles; 2002) chapter 1, at page 17.

³ This turn of phrase stems from Luhmann's thesis, in which he cites 'the paradox of prevention': Luhmann, N. *Risk: A Sociological Theory* (Walter de Gruyter; Berlin; 1993) at page 29. The paradox is that, although the very notion of anticipatory action is essentially an acknowledgment that the future is uncertain, we continue to "actively [seek] out confirmation of the assumption that the course of events will remain amenable to control" (at page 29). He concludes that risk-elimination remains a risk (at page 30).

within Beck's understanding of 'current action'. However, Beck argues that uncertain risks "can only be dealt with retroactively".⁴ On the basis of the Beck's notion of current anticipatory action, therefore, the precautionary principle is inoperable. There is no basis for precautionary decision-making because there lacks specific knowledge in relation to the occurrence and magnitude of potential hazards.

Beck's argument that hazards in industrial society are statistically predictable, whilst those in risk society are unpredictable, brings to light an interesting dilemma for the precautionary principle. His thesis works on the premise that, given that threats in the industrial can be quantified, future events, even though they have not yet occurred, can become the object of current action. Conversely, post-industrial risks that are incalculable and uncertain cannot become the object of current action. Beck considers that the inherent scientific ambiguity surrounding hazards of risk society makes it impossible to control their occurrence or minimise their impact prior to their According to Beck, the uncertainty manufactured by reflexive materialisation. modernisation creates a conflict with anticipatory action.⁵ From this perspective, therefore, the precautionary principle can only operate in response to *calculable* and scientifically certain threats that are associated with Beck's industrial society. Conversely, the precautionary principle is unworkable in his post-industrial risk society.

This position is wholly incompatible not only with the 'working definition' of the precautionary principle, but also with its underlying objectives. Principle 15 of the Rio Declaration states that:-

"[w]here there are threats of serious or irreversible damage, *lack of full* scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."⁶

The application of the precautionary principle depends on there being a degree of scientific *un*certainty in relation to potential environmental hazards. Contrary to

⁴ Beck, U. and Willms, J. *Conversations with Ulrich Beck* (Polity Press; Cambridge; 2003) at page 135. ⁵ Beck, U. and Willms, J. (2003) at page 31.

⁶ The United Nations Conference on Environment and Development (UNCED) Declaration, Rio de Janeiro, 1992, emphasis added.

Beck's argument, and as this definition demonstrates, the precautionary principle as an instrument of current action to manage future events, is intended to operate only in relation to scientifically *un*certain hazards – such as those characteristic of Beck's risk society.

This gives rise to an illogical state of affairs. The argument that current action can only be retroactive, not proactive, generates a situation in which either the precautionary principle is theoretically feasible but never invoked, or desirable but unworkable. Although he claims that current action is viable in industrial society because hazards are scientifically-certain, precautionary responses to hazards are futile by virtue of their statistical certainty and perceived controllability. Precaution in risk society, on the other hand, presents an appropriate approach to the unknown, although, according to Beck, is inoperable because global, imperceptible, and sporadic hazards cannot become the object of anticipatory decision-making.

This stance is not only pessimistic,⁷ but it is also inconsistent with the affiliation between precaution and diminished scientific authority. Although Beck's modernity thesis is useful in explaining the emergence of a precautionary-mindset, his model of current action undermines its implementation. With this in mind, it is useful to consider the notion of precaution in terms of 'responsibility' – first, because it provokes a broader scrutiny of precaution; and second, because it substantiates the argument that the *dis*-embedding of scientific authority through the precautionary principle and the subsequent *re*-embedding of authority through reliance on risk assessment places a constraint on securing responsibility for the impact of decision-making. The following section shows that the imposition of responsibility through the precautionary principle is limited by the institutional failure of science to articulate threats that do not fit conventional models of prediction.

Having benefited from an understanding of the relationship between science, risk definitions and theories of social constructivism, this section assesses the extent to which the precautionary principle can provide us with an 'ethics for the future'. It focuses primarily on the seminal work of Hans Jonas, *The Imperative of*

⁷ This pessimism is evident in Beck's sentiment: "Yep, there's no way out, we leave you, to your overcivilized fate", Beck, U. and Willms, J. (2003) at page 204.

Responsibility, and interposes Jonas' theory of future-oriented ethics on the ideals of precaution. It finds that, despite the depiction of the precautionary principle as a manifestation of Jonas' construction of responsibility for decisions made in the face of an unknown future, the ability of the precautionary principle to attribute responsibility in practice is offset by an embedded culture of formal scientific discourse and the judicial review of decision-making. The upshot is that, whilst the precautionary principle is an ostensible mechanism for furnishing decision-making with a cognisance for the unpredictable future, its implication is curbed by a continuing reliance by policy-makers on scientific fact, extrapolated from past experience.

In order to demonstrate the disparity between scientific and precautionary decisionmaking, it is useful to draw upon the seminal work of Hans Jonas – *The Imperative of Responsibility*.⁸ Interestingly, despite the fact that Ulrich Beck's is frequently hailed as *the* founding author in the fields of risk and modernity,⁹ Jonas had identified that the modern condition presented a new ethical challenge to the traditional control of ecological hazards almost a decade before the publication of Beck's *Risk Society*.¹⁰ It is, thus, surprising to find that Jonas' work tends to be overlooked in studies of technologically-generated hazards.

9.2 Conceptual inappropriateness

As Jonas observes:-

"the doer, deed, and effect are no longer the same as they were in the [individual] proximate sphere, and which by the enormity of its powers forces upon ethics a new dimension of responsibility never dreamed of before."¹¹

⁸ Jonas, H. (1979).

⁹ See, for example, McDonell, G. 'Risk Management, Reality and the Precautionary Principle: Coping with Decisions', in Harding, R. and Fisher, E. (eds) *Perspectives on the Precautionary Principle* (Federation Press; Sydney; 1999) chapter 10 at page 200.

¹⁰ Beck, U. Risk Society: Towards a New Modernity (Sage; London; 1992).

¹¹ Jonas, H. (1979) at page 6.

Broadly speaking, Jonas concludes that science is incapable of providing us with an 'ethics of the future'. It has long been recognised that scientific prediction of the occurrence and magnitude of future hazards is extrapolated from observed past events. However, the practice of looking to the past to explain the future ignores the fact that the accuracy with which the past can be extended into the future is wholly dependent on the future mirroring that which has already occurred. And, as experience has shown, much of the future transpires in a unique and detached manner, independent of precedent. Jonas notes that "an extrapolation from presently available data will always, in certainty and completeness of prediction, fall short of the causal pregnancy of our technological deeds."¹² The upshot is that scientific decisionmaking is incapable of being mindful of potential and eventual long-term impacts.¹³ This inevitably creates a 'gap' in responsibility. Given that science cannot meaningfully engage with the unknown, it is incapable of establishing responsibility for future hazards.¹⁴ Adam refers to this as the 'structural irresponsibility' of science.¹⁵

In order to illustrate his argument, Jonas reflected on the nature of 'traditional' ethics and their inability to ascribe responsibility for latent consequences of decisionmaking. Ethics directly relate to human action – "whether in the form of issuing direct enjoinders to do and not to do certain things, or in the form of defining principles for such enjoinders, or in the form of establishing the ground of obligation for obeying such principles".¹⁶ Jonas observed that the nature of human action in the modern era has significantly altered.¹⁷ Naturally, this change should be accompanied by a change in ethics.¹⁸ Yet, the framework of traditional ethics still underpins the construction of responsibility.

Jonas explained that this traditional framework treated *techne* as an ethically neutral realm.¹⁹ Since technological enterprise did not interrupt the balance of nature, and

¹² *Ibid.* at page x.

¹³ Adam, B. (2004) at page 5.

¹⁴ *Ibid.* at page 6.

¹⁵ *Ibid.* at page 4; Beck calls it the 'non-responsibility of science', see Beck, U. (1992) at page 214.

¹⁶ Jonas, H. (1979) at page 1.

¹⁷ *Ibid.* at page 6.

¹⁸ *Ibid.* at page 1.

¹⁹ *Ibid.* at page 4.

given that there was no question of it causing permanent injury to the integrity of the nonhuman world, it was regarded as being ethically insignificant.²⁰ In this sense, ethical significance was attributed only to activities that influenced humankind. For the most part, traditional ethics were anthropocentric, and this was evident in its maxims – such as 'Love thy neighbour as thyself', and 'Do unto others as you would wish them to do unto you'.²¹

This anthropocentricity is explained with reference to the confines within which ethics traditionally operated. First, they were limited in space. That is, they functioned in a localised manner, in the 'proximate sphere'²² between friends, neighbours, and so on, within the bounds of human interaction. Second, their operation was limited in time, confined to the foreseeable within the span of human life.²³

These spatial and temporal constraints were reflected in the knowledge base required to ensure that human action was consistent with ethical maxims. Jonas claimed that, as a result of their localised and short-term bearing, ethics in the traditional framework needed to be buttressed by 'ordinary' intelligence (as opposed to expertise) – that is, knowledge informed by, and accessible to, the general populace. However, Jonas detected that the modern age presented novel technological hazards – their occurrence and magnitude extending beyond the containment of 'nearness and contemporaneity'.²⁴ The inability of traditional ethics to cultivate control over global and long-term impacts reveals not only the vulnerability of nature, but also the phenomena that mankind is a causal agent in environmental degradation.²⁵ This plight of nature creates new dimensions of responsibility.

In a similar vein to Beck's theory of *reflexive modernisation*,²⁶ Jonas describes the technological era as 'cumulatively self-propagating'.²⁷ Modernity generates hazards

²⁰ Ibid.

²¹ *Ibid.* at page 5.

²² *Ibid.* at page 6.

²³ *Ibid.* at page 5.

²⁴ Jonas, H. (1979) at page 7.

²⁵ *Ibid.* at page 6.

²⁶ See, for example, Beck, U. and Beck-Gernsheim, E. *Individualization* (Sage; London; 2002) at page 151.

²⁷ Jonas, H. (1979) at page 7.

of unprecedented nature, frequency and scale, making them impossible to predict and control using past observations. The uncertainty of the future elevates the import of knowledge, leading to increasing scientific specialisation and reliance on expertise. Paradoxically, however, this escalation in the value of scientific knowledge is juxtaposed against its increasing inability to know the future. Jonas remarks that science generates:-

"conjectural knowledge of the real and the probable in the realm of facts is thus interposed between the ideal knowledge of ethical principles and the practical knowledge of political application, which must operate with such hypothetical projections of what hope or fear have to expect - what to promote and what to prevent."²⁸

He goes on to note that:-

"[a]s long as the danger is unknown, we do not know what to preserve and why. Knowledge of this comes, against all logic and method, from the perception of what to avoid. This is perceived first and teaches us, by the revulsion of feeling which acts ahead of knowledge, to apprehend the value whose antithesis so affects us. We know the thing at stake only when we know that it is at stake."²⁹

Thus, until it has transpired, the future is unknowable. Inferring the future from past events requires "an exponentially higher degree of science than is already present in the technology from which it is to be extrapolated."³⁰ Therefore, knowledge of the implication of future hazards is forever 'not yet available'.³¹ The inherent uncertainty of long-term predictions renders ineffectual responsibility for future implications of decision-making.³² In recognition of the futility of extrapolation, Jonas calls for a more 'future-oriented' framework of ethics as a means of attributing responsibility.³³

²⁸ *Ibid.* at page 26.
²⁹ *Ibid.* at page 27.
³⁰ *Ibid.* at page 29.

³¹ Ibid.

³² *Ibid.* at page 30.

³³ *Ibid.* at page 12.

9.3 Control and responsibility

Jonas identifies two different types of 'responsibility' – first, responsibility in the 'formal' sense of accountability; and second, responsibility in the 'substantive' sense that someone is a responsible person, i.e., that he or she honours his or her duties or responsibilities.³⁴ Whereas the former type is backward-looking in that it is dependent on a degree of causal attribution between a decision and its consequences, the latter is "a forward determination of what is to be done".³⁵ This distinction is critical to Jonas' thesis. For him, formal responsibility is an 'empty' concept because it constructs a *legal*, rather than *moral*, form of accountability.³⁶ By virtue of the principle of causal attribution, a formal responsibility to indemnify can exist independently of feelings of guilt.³⁷ In other words:-

"The damage done must be made good even if the cause was no misdeed, and even if the consequence was neither foreseen nor intended. It suffices that I was the active cause – but then again only in close causal connection of the consequence with the deed, so that the attribution is clear and the consequence does not lose itself in the unforeseeable."³⁸

This formal type is incapable of manufacturing 'responsibility for the future' because reality has shown that the consequences of modernity transcend the spatial and temporal constraints of causal attribution.

Jonas comes to the following conclusion:-

"For it is the future of the whole existence, beyond the direct efficacy of the responsible agent and thus beyond his concrete calculation, which is the invisible co-object of such a responsibility in each of its single, defined occasions. These occasions, and the interventions they provoke, are each time about the proximate particular, and this lies more or less

³⁴ *Ibid.* at page 98.

³⁵ *Ibid*. at page 92.

³⁶ *Ibid.* at pages 90-92.

³⁷ *Ibid.* at page 91.

³⁸ *Ibid.* at page 90.

within the range of informed prescience. The totality that will absorb the long-range effect of the particular decision is beyond such prescience, not only because of the unknown number of unknowns in the equation of objective circumstances, but ultimately because of the spontaneity or freedom of the life in question – the greatest of all unknowns, which yet must be included in the total responsibility."³⁹

This leads Jonas to refer to futurity as 'self-owned',⁴⁰ suggesting that the future is its own guardian of unpredictability. In other words, under the blinkered framework of traditional ethics, decisions are made without regard for their latent spatial and temporal impact. Naturally, it is irrational to suppose that responsibility can be attributed for consequences of which the decision-maker was neither aware, nor should have been aware.

It is against this backdrop of 'structural irresponsibility' that the continuing societal tendency to rely on scientific expertise in decision-making appears all the more conspicuous. It is interesting to observe the preservation of scientific dominance in an age when science has been proven to have been mistaken in its predictions of the future. A plausible explanation for the supremacy of scientific knowledge lies in the social desire to establish a legitimate basis for decision-making, which manifests itself in a 'compensation culture' and "erodes our faith and trust in each other and even ourselves."⁴¹ Scientific knowledge has a crucial role in imparting legitimacy to publicly scrutinized decision-making, despite the fact that science is exposed to the criticism that "opinion is the only possible approach to the future".⁴²

The precautionary principle can be seen as an attempt to circumvent the structural irresponsibility of the formal discourse of science and create an 'ethics of the future', imposing responsibility for future long-term impacts. On an abstract level, subscription to the spirit of precaution is a way of assigning moral responsibility for consequences that were unknown at the time of decision-making, thus establishing a

³⁹ Ibid. at page 107.

⁴⁰ Ibid.

⁴¹ Durodié, B. 'Trust Comes from Expertise', in Gilland, T. et al, Debating Matters: Science: Can We Trust the Experts? (Hodder & Stoughton; London; 2002) Essay Two, at page 30.

⁴² Luhmann, N. Risk: A Sociological Theory (Walter de Gruyter; Berlin; 1993) at page 214.

duty to show concern for future generations, in an unknown time and space.⁴³ In essence, it is an implicit acknowledgement that techno-scientific progress surpasses traditional spatial and temporal confines that are conducive to scientific certainty in prediction. From this perspective, and in keeping with the aims of sustainable development, the notion of precaution allows us to extend ourselves beyond the present without having to rely on extrapolation. It perceives the future as unknowable and uncontrollable, and accepts that it is impossible to measure and comprehend future hazards unless, and until, they have materialised.

The precautionary principle is born of the assumption is that "the damaging effects of human activities may become irreversible before the scientific community can agree the precise nature or scope of their impact".⁴⁴ In this sense, it introduces a process of artificial and premature closure to decision-making. Given the uncertainty with which a threat may present itself, precautionary action must be taken before its spatial and temporal impact can be ascertained. Von Moltke explains that:-

"[s]cience almost never provides clear proof of major environmental impacts because the environment is too complex to be comprehensively described in strictly scientific terms. For example, despite widespread acceptance of the firm hypothesis that greenhouse gases are capable of trapping heat exist, science remains almost incapable of answering critical questions concerning actual environmental responses to changes in their concentration in the atmosphere."45

This forms the bedrock of Jonas' argument. The limitations of science to produce sufficiently predictive knowledge - described as a 'disparity between power and competence^{,46} – places an 'impossible strain'⁴⁷ on securing responsibility for the ecological impact of action. Thus, rather than relying on scientific knowledge to be

⁴³ See Jonas, H. (1979) at page 128.

⁴⁴ Holder, J. 'The Precautionary Principle Under UK Environmental Law', in Holder, J. Impact of EC Environmental Law in the UK (Wiley; Chichester; 1997) at page 123.

⁴⁵ von Moltke, K. 'The Relationship between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle', in Freestone, D. and Hey, E. (1996) chapter 6, at page 98, emphasis added. ⁴⁶ Jonas, H. (1979) at page 93.

⁴⁷ *Ibid.* at page 107.

mindful of the future,⁴⁸ Jonas proposes that morality is better equipped to establish responsibility than science. Accordingly, moral responsibility can extend farther than proximate consequences of decision-making, thus overcoming the problems of precognition. Jonas does note, however, that moral responsibility will only be effective if it surpasses the 'critical point of moral theory', meaning that there must be a shift in stimulus – from *willingness* to *obligation*.⁴⁹

Although Jonas fails to provide any further clarification of this transition, it is possible that his notion of 'obligation' might be construed in a legal sense. As Part One of this thesis has illustrated, despite the fact that the precautionary principle appears in the text of a number of legal provisions at international, EC and domestic levels, the nature and extent of the obligation it imposes remain unclear. On the basis of Jonas' theory that the reliance on scientific foresight antagonises the ascertainment of formal responsibility, it can be said that the practice of using scientific risk assessment to determine the application of precaution limits the extent to which responsibility for impending hazards might be attributed.

This brings to attention the discord between the forward-looking nature of precaution and the backward-looking nature of scientific risk assessment. The precautionary principle is less able to secure responsibility for hazards whose quality and impact are unknown because risk assessment processes utilise observations of the past to predict the future. Despite the fact that the precautionary principle represents a *prima facie* ethical basis for responsibility of future impacts, its ability to achieve such implication is curtailed by the institutionally-embedded predicament of science. In other words, although the precautionary principle is portrayed as a being a tool to close the responsibility gap, its ability to do this is restricted because decision-making institutes remain bound by the narrow scope of scientific foresight.⁵⁰

⁴⁸ Adam, B. 'Re-Vision: The Centrality of Time for an Ecological Social Science Perspective', in Lash, S. et al (eds) Risk, Environment and Modernity – Towards a New Ecology (Sage; London; 1996) chapter 3, at pages 98-99.

⁴⁹ Jonas, H. (1979) at page 129.

⁵⁰ Beck makes a similar argument, stating that:-

[&]quot;[t]he promotion and protection of 'scientific progress' and of 'the freedom of science' become the greasy pole on which the primary responsibility for political arrangements slips from the democratic political system into the context of economic and techno-
Although responsibility might formally be attributed to scientists or politicians who base their decisions of scientific knowledge of the future, it is of little practical consequence. Value-laden decisions can be defended on the ground that they relied on 'sound science'. Any undesirable consequences of decision-making are accredited to knowledge that displayed scientific traits of rationality and certitude. The innate legitimacy, therefore, of scientific means of prediction is counteracted by its inability to know the future. Attaching responsibility through the precautionary principle is likely to be a futile exercise because its own capacity to ascertain the likely consequence of potential hazards is offset by its scientific basis of its application. The result is that, despite the fact that the precautionary principle is presented as a means of establishing a dialogue with the undesirable impacts of technological advance, the ability of precaution to develop a consciousness for the future is undercut by the scientific domination of risk decision-making.

In the face of risk-complexity – the need for 'decidability' increases, but decisions are increasingly disabled.⁵¹ Decisions are *disabled* because risks are *incalculable*. Accordingly:-

"the catastrophic potential of an increasing number of our ... industrial activities has magnified beyond the comprehensible (e.g. Chernobyl, biochemical warfare, genetics). The established institutionalization of 'risk' in terms of 'insurance' (coupling risk with money and the future) has collapsed because it has become clear that this catastrophic potential can no longer be grasped in the form of the commodity fetish to which money is related. The probability/magnitude nexus of this catastrophic potential thus becomes incalculable in so far as it has lost its ultimate point of reference. Hence, as the need for more complex and more precise

scientific non-politics, which is not democratically legitimated." (Beck, U. (1992) at page 186).

⁵¹ Adam, B. and Van Loon, J. 'Introduction: Repositioning Risk; the Challenge for Social Theory', in Adam, B. *et al* (eds) (2000) at page 13; see also Adam, B. 'Values in the Cultural Timescapes of Science', in Lash, S. *et al* (eds) *Time and Value* (Blackwell; Oxford; 1998) pages 227-244.

calculations rises with the increased complexity of risk, so does the impossibility to establish such calculations."⁵²

The precautionary principle is presented as a means through which decisions can be made in the absence of certainty. It can be interpreted as encouraging decidability in the face of the unknown. Yet, in the light of the fact that the instigation of precautionary responses is traditionally governed by risk calculation, it can be argued that the operation of the precautionary principle is equally disabled.

Part Three of this thesis provides a detailed examination of the UK BSE epidemic. It illustrates that the utility of precaution in the face of threats posed by the bovine disease was undermined by an institutional focus on scientific *knowns*, as opposed to *unknowns*.

⁵² Adam, B. and Van Loon, J. (2000) at page 13.; see also Adam, B. (1998); and, Colborn, T. et al, Our Stolen Future (Plume; New York; 1996); Ratzan, S. C. The Mad Cow Crisis: Health and the Public Good (University College Press; London; 1998) at page 13.

Part Three

<u>Case study: Bovine Spongiform Encephalopathy; scientific</u> risk assessment, risk regulation and the role of precaution

"For the majority of administrative lawyers ... expertise and science have been transplantable black boxes that can be slotted into any particular area of the law. These different boxes are rarely opened up and subjected to critical analysis."⁵³

⁵³ Fisher, E. 'The Rise of the Risk Commonwealth and the Challenge for Administrative Law' (2003) *Public Law* 455, at page 467.

Chapter Ten

<u>A case study: the BSE episode. Evidence of the institutional</u> <u>marginalisation of uncertainty, the supremacy of scientific risk</u> <u>assessment, and the limited impact of precaution</u>

10.0 Introduction

The Government's handling of the BSE crisis from the mid 1980s onwards has generated fervent criticism of, and remorse for, the way in which the episode panned out. Millstone, for example, counts the saga as "the single biggest failure of UK public policy since the Suez debacle of 1956".¹ Jacob and Hellström describe it as "one of the most costly public policy crises of the decade"² and "an institutionally predicated crisis of risk management."³

There is little doubt amongst academic commentators, politicians, scientists, and the public at large, that the BSE crisis was indicative of the limits of human intervention in nature.⁴ It stands out in history as marking the point in contemporary society at which mistrust in scientific evidence was prevalent, bringing into sharp focus the fallibility of traditional images of the controllability and certitude of the future. Existing literature tends to frame it as a defining moment in the demise of the longstanding supremacy of scientific knowledge in risk analysis,⁵ depicting the episode as archetypal evidence of the constraints of conventional models of prediction.

¹ Millstone, E. 'When, Where and Why Does Evidence Matter to Policy-Makers?', a transcript of a talk at the Overseas Development Institute (ODI) 30 April 2003, see <u>http://www.odi.org.uk/rapid/Meetings/Evidence/Presentation_Millstone.html</u>, accessed in November 2004.

² Jacob, M. and Hellström, T. 'Policy Understanding of Science, Public Trust and the BSE-CJD Crisis' (2000) 78 Journal of Hazardous Materials 303-317, at page 305.

³ Ibid. at page 306.

⁴ Vos, E. 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 Journal of Consumer Policy 227-255, at page 227.

⁵ Beck, U. and Willms, J. Conversations with Ulrich Beck (Polity Press; Cambridge; 2003) at pages 121-128.

The admission by the Government in March 1996 that there might be a link between BSE in cattle and new variant Creutzfeldt Jakob Disease ('CJD') in humans prompted fierce debate over the relationship between science, risk, law, and precaution. Given that the Government chose legislation as the principal vehicle through which the disease could be controlled, an analysis of the interface between the legal response to BSE and notions of risk and scientific certitude is of utmost importance. In particular, the BSE episode draws attention to the inter-relationship between the legal regulation of uncertainty and science, highlighting that modernity has placed new demands on scientific prediction which have undermined the legitimacy of the dependence of law on notions of scientific certainty, reason, and rationality. One of the remarkable achievements of the modern risk society has been the reconstruction of the concepts of 'sound science' and 'expertise'. This has led to the recognition that claims made by science to objectivity are severely destabilised by the relativist position, and that, contrary to traditional scientific thinking, the notion of expertise is both highly specific and at the same time is able to encompass an extraordinarily wide range of knowledge-holders. However, despite a full-frontal attack on the philosophical underpinnings of science, the fundamental principles of objectivity, rationality, certitude, and expertise continue to be prominent in the assessment of risk. That is to say, whilst there is some disciplinary acknowledgement of the contribution made by the social sciences in relation to the problems of indeterminacy, contradiction and uncertainty, the practice of risk analysis confirms that the formal discourse of physical science is authoritative in its understanding of the world.

The reliance of risk assessment on science is evident throughout the administration of the BSE epidemic. In particular, the analogy drawn between BSE in cattle and scrapie in sheep (the 'scrapie analogy') illustrated that scientific risk assessment was based on the notion that observations of past events could be projected into the future as a means of prediction. By applying the knowledge that scrapie was incapable of transmitting to humans, Government scientists were able to conclude that it was highly unlikely, if not implausible, that BSE would pose a risk to human health. Yet, as the following excerpt from Bernstein's *Against the Gods: The Remarkable Story of Risk* shows, calculating the magnitude and scale of future events on the basis of knowledge of the past is often a futile exercise. He states that:-

"[w]e cannot enter data about the future into the computer because such data are inaccessible to us. So we pour in data from the past to fuel the decision-making mechanisms created by our models, be they linear or nonlinear. But therein lies the logician's trap: past data from real life constitute a sequence of events rather than a set of independent observations, which is what the laws of probability demand. History provides us with only one sample of the economy and the capital markets, not with thousands of separate and randomly distributed numbers. Even though many economic and financial variables fall into distributions that approximate a bell curve, the picture is never perfect. Once again, resemblance to the truth is not the same as truth. It is in those outliers and imperfections that the wildness lurks."⁶

The failure of the Government to recognise the fallibility of its predictions that the human consumption of BSE-infected meat was safe is central to the following study of the intersection between law and science. It is important to note that, in using the term 'science', there is a distinction between the *individual* scientist and science as an *institution*. Such as distinction is as inevitable as it is necessary, for it cannot be assumed that any activity undertaken by a scientist is to be automatically regarded as 'sound science'. Flaws in the scientific assessment of the risk of BSE are attributable to the institution of science, and criticism of the idealistic notions of objectivity and certitude are directed towards the formal discourse of science.⁷

- b. Ignoring the fundamental role of uncertainty; and
- c. Dismissing aspects of 'organisational culture'.

⁶ Bernstein, P. L. Against the Gods: The Remarkable Story of Risk (John Wiley & Sons; New York; 1996) at page 335.

⁷ Jones, B. D. identifies three aspects of formal scientific discourse in the policy-making:-

a. Isolating out one motive from a panoply of those that drive congressional behaviour;

These themes of precision and impartiality pervade conventional analyses of the formal discourse of science. See Jones, B. D. 'Bounded Rationality and Political Science: Lessons from Public Administration and Public Policy' (2003) 13(4) *Journal of Public Administration Research and Theory* 395-412, at pages 405-406. This argument reflects Jasanoff's argument that "science is ordinarily seen as set apart from all other social activities by virtue of its institutionalized procedures for overcoming particularity and context dependence and its capacity for generating claims of universal validity." See Jasanoff, S. *Science at the Bar: Science and Technology in American Law* (Harvard University Press; Harvard; 1997) at page 7.

To a large extent, the problem of ascertaining the 'proper' role of science in risk decision-making remains unresolved. The aim here is not to propose an exhaustive model of a more pragmatic relationship between law, science, and risk. Instead, it uncovers some of the major themes arising from the regulation of BSE, with specific reference to the notion of scientific certainty and the precautionary principle. Furthermore, whilst this study exposes the weaknesses in the management of BSE and comments on the more abstract liaison of law with science, its focus does not stray too far from the sobering reality of the human impact of CJD. Even though issues relating to the legislative response to scientific uncertainty, definitions of risk, and the role of precaution form the substance of this examination, it is important that the gravity of the human health implications of BSE are not altogether overlooked.

The BSE episode was unique in that it brought about an unprecedented consumer backlash against official advice. The crisis in consumer confidence in the safety of beef⁸ played a key role in the Government's repeated assertions that, as a matter of scientific fact, the BSE agent was incapable of jumping the species barrier from cattle to humans. Moreover, the epidemic effectively reduced the ostensible distance between the consumer and the agricultural industry, effectively shortening the supply chain. As a result of this newfound proximity, consumers suddenly became key players in the social construction of risk. As Chambers observes:-

"[t]he link between the bright red, clean meat which appears on white plastic trays wrapped in cling film on supermarket shelves and the animals – stunned, killed, bled, eviscerated and sawn up on production lines in the slaughterhouse – has not always been obvious to the public now for many years."⁹

The BSE crisis had an enormous impact on the way in which consumers perceived bovine products, triggering deep-rooted public anxiety about the credibility of scientific evidence and the sincerity of Government assurances that BSE posed a minimal danger to consumers. Provoked by intense media interest, commentators

⁸ Donnelly, C. A. et al 'A Review of the BSE Epidemic in British Cattle' (1999) 5(3) Ecosystem Health 164-173, at page 165.

⁹ Chambers, G. R. 'The BSE Crisis and the European Parliament' in Joerges, C. and Vos, E. (eds) *EU* Committees: Social Regulation, Law and Politics (Hart Publishing; Oxford; 1999) 95-106, at page 97.

were quick to interpret the Government's insistence on a firm scientific basis for action as a "barely concealed conspiracy"¹⁰ or "an easy way in which its own uncritical support for the agriculture and food industries could be justified."¹¹ Without doubt, the strict reliance on arguments derived from scientific evidence raises contentious issues about the role of science in risk assessment and the formulation of legislation. The Government's staunch adherence to scientific findings continued throughout the episode, in spite of the fact that there was evidence to suggest that the adoption of the precautionary principle would have better suited the political needs at that time.¹²

Although a narrative account of events is necessary in order to set the scene, this case study aims to avoid simply reproducing findings already documented in the Phillips Inquiry. It is hardly surprising that, given that the disease was first acknowledged almost twenty years ago, a vast amount of literature has been generated during that time. Retrospective studies of the spread and impact of the disease have tended to present a narrative of events, without exploring the finer details of the interplay between science, uncertainty, and the regulation of risk through legal provisions. This case study avoids reproducing previously documented findings, and examines how the framing of risk definitions had a critical bearing on the application of the precautionary principle and, more generally, on the regulation of the future via the law.

10.1 BSE and scientific supremacy

If nothing else, the BSE crisis is a textbook example of the exclusivity of risk definitions fostering scientific supremacy. In particular, this chapter explains that the authority bestowed upon scientific opinion throughout the entire episode was reflective of two major aspects of decision-making. First, the reductionist and deterministic characteristics of scientific discourse generate abstract and universal numerical expressions of chance, allowing risk governance to be based on specific

¹⁰ Winter, M. 'Intersecting Departmental Responsibilities, Administrative Confusion and the Role of Science in Government: the Case of BSE' (1996) 49(4) Parliamentary Affairs 550-565, at page 561.

¹¹ Ibid.

and seemingly uncontested knowledge. The conviction with which evidence was presented, particularly during the early years of the BSE crisis, was indicative of the underlying scientific assumptions of quantification and certitude. Indeed, prior to official acknowledgement that CJD might be associated with the consumption of infected bovine products, the official standpoint was founded on the notion that the threat of transmission was ascertainable, and was known to be low.

Second, uncertainty in respect of the transmission of BSE to humans itself heightened both expert and public consciousness of unpredictable consequences, triggering an increase in the demand for a secure future. Paradoxically, and notwithstanding the implicit recognition of the limits of scientific prognoses, the role of science in assessing the unknown was elevated above lay predictions as a means of recreating certainty through statistics. Political pressures to control public fear and to protect the commercial interests of agricultural export placed impossible demands on Government Ministers to suppress the communication of uncertainty, and construct a controllable and definable risk. To a large extent, the manufacturing of certainty is evident in the scientific analysis of the threat posed. Any gaps in knowledge of the cause, transmissibility, infectivity, and incubation period of the BSE agent were implicitly plugged by political and commercial objectives, meaning that the scientific definition of risk was surreptitiously shaped by the context of its construction.

The investigation begins with a study into the way in which the threat of the transmission of BSE from cattle to humans was represented. It shows that, despite the indisputable uncertainty of both the likelihood and impact of transmission, the possibility of BSE jumping the species barrier was presented as a *known* risk. Instead of acknowledging that the BSE agent posed a threat beyond the capacity of human knowledge, it was depicted as being an identifiable and definite risk. Statements about human susceptibility to the disease were made on the basis that there was a statistically-determined risk of infection between zero and one. This risk-based modelling of exposure to the human population, conducted before March 1996, led to affirmative conclusions that the risk of transmission was either non-existent, or negligible. Ministers and Government scientists made assertions within the parameters of the definition of risk – claiming either that "BSE is most unlikely to

have any implications for human health"¹³ (i.e. low risk), or that "we can say with confidence that beef can be eaten safely by everyone, both adults and children"¹⁴ (i.e. no risk).

The impact of this risk discourse was profound, proving to be a pivotal factor in the shaping of subsequent legislative provisions. In order to demonstrate the effect of what might be called 'the bureaucracy of risk', it is argued that the use of the term 'risk' during the BSE episode secured, by virtue of its innate exclusivity, the supremacy of scientific opinion. Instead of acknowledging the uncertainty with which BSE manifested itself, the Government's uncontested reliance on the findings of 'establishment' expertise was testimony not only to the underlying tenets of scientific prediction, but also to a political desire to exercise control over the unknown.

10.2 What are TSEs?

Winter is right to observe that the presence of TSEs in animals is not a new phenomenon – they have been detected in a number if different species for some time,¹⁵ manifesting as scrapie in sheep and goats, Chronic Wasting Disease (CWD) in wild deer in North America, and Transmissible Mink Encephalopathy (TME).¹⁶ Human TSEs include Creutzfeldt-Jakob Disease (CJD), Grestmann-Sträussler Syndrome (GSS), kuru, and Fatal Familial Insomnia (FFI).¹⁷ TSEs are characterised by small vacuoles in the brain, leading to progressively severe psychomotor dysfunction.¹⁸ In 1982, Prusiner discovered that the infectious agents of TSEs were infectious proteins or 'prions' (proteinaceous infectious particles).¹⁹ He found that prions are transmissible particles composed exclusively of modified protein. Protein can exist in both toxic and non-toxic isoforms. Prusiner suggested that toxic isoforms

¹³ Cited in Consumers in Europe Group, BSE: Briefing and Recommendations from Consumers in Europe Group (Consumers in Europe Group; London; 1996) at page 4.

¹⁴ John Gummer (Minister of Agriculture, 1989-93) HC Debates 21 May 1990 at page 82.

¹⁵ Winter, M. (1996) at page 551.

¹⁶ Prusiner, S. B. 'Prion Diseases and the BSE Crisis' (1997) 278 Science 245-51, at page 245.

¹⁷ Ibid.

¹⁸ Donnelly, C. A. *et al* (1999) at page 165.

¹⁹ Prusiner, S. B. 'Novel Proteinaceous Infectious Particles Cause Scrapie' (1982) 216 Science 136-144.

are capable of converting non-toxic counterparts, resulting in the self-propagation of infectious cells. Brain damage is thought to occur when abnormal prion protein enters into the brain causing normal protein to adopt a new, infectious, structure.²⁰

It is possible that scrapie in sheep was identified as early as the eighteenth century,²¹ although the first *published* commentary of the disease appeared in 1913.²² It is a globally endemic condition, except in Australia and New Zealand, and clinical symptoms include nervousness, pruritis, and lack of coordination.²³ Early studies claimed that scrapie was a hereditary condition. However, in 1936 Cuille and Chelle established that it could be transmitted by the exposure of sheep to affected sheep brain.²⁴ Subsequent studies were successful in transmitting scrapie to goats,²⁵ mice,²⁶ and hamsters²⁷ through contact with infected tissue.

Approximately 200 years after the first clinical identification of scrapie, a TSE affecting humans was recognised by Creutzfeldt²⁸ and Jakob.²⁹ The disease later became known as 'Creutzfeldt-Jakob disease' (CJD). Although relatively little is known about CJD in comparison with other TSEs, it is thought to be a rare disease, on a global scale affecting approximately one in a million people per year.³⁰ There is a

²⁰ Chesebro, B. 'Enhanced: BSE and Prions: Uncertainties About the Agent' (1998) 279(5347) Science 42-3, at page 42.
²¹ Some commentators claim that scrapie was first identified in 1720 – see, for example Donnelly, C.

²¹ Some commentators claim that scrapie was first identified in 1720 – see, for example Donnelly, C. A. *et al* (1999) at page 165; and, Parry, H. B. 'Scrapie: A Transmissible and Heredity Disease of Sheep' (1962) 17 *Heredity* 75-105. The BSE Inquiry Report, on the other hand, claims that the first record of the disease was made in 1732: see *The Inquiry into BSE and Variant CJD in the United Kingdom* (HMSO; London; 2000) referred to as the 'BSE Inquiry' hereafter, in particular, Volume 2, Chapter 2, page 22, at section 2.10.

²² Stockman, S. 'Scrapie: An Obscure Disease of Sheep' (1913) 26 Journal of Comparative Pathology 317-327.

²³ BSE Inquiry (2000): Volume 2, Chapter 2, page 21, at section 2.7.

²⁴ See Cuillé, J. and Chelle, P. L. 'La maladie dite tremblante du mouton est-elle inoculable?' (1936)
203 Comptes Rendus Des Seances de l'Academie de Sciences 1552-1554.

²⁵ Pattison, I. et al (1959) 'Experimental Production of Scrapie in Goats' (1959) 69 Journal of Comparative Pathology 300-312.

²⁶ Chandler, R. (1961) 'Encephalopathy in Mice Produced by Inoculation with Scrapie Brain Material' (1961) 277(7191) *The Lancet* 1378-1379.

²⁷ Marsh, R. and Kimberlin, R. (1975).

²⁸ See Creutzfeldt, H. G. 'Über eine eigenartige herdformige Erkrankung des Zentralnervensystems' (1921) 57 Zeitschrift für die gesamte Neurologie und Psychiatrie 1-18.

²⁹ See Jakob, A. 'Über eigenartige Erkrankung des Zentralnervensystems mit bemerkenswertem anatomischen Befunde: (spatische Pseudosklerose-Encephalomyelopathie mit disseminierten Degenerationsherden)' (1921) 64 Zeitschrift für die gesamte Neurologie und Psychiatrie 147-228; Jakob, A. 'Über eine der multiplen Sklerose klinishe nahestehende Erkrankung des Zentralnervensystems (spatische Pseudosklerose) mit bemerkenswertem anatomischen Befunde: Mitteilung eines vierten Falles' (1921) 17 Medicine Klinik 372-376.

³⁰ BSE Inquiry (2000) Volume 2, Chapter 2, page 24, at section 2.21.

risk, however, that its prevalence is underestimated since its symptoms are consistent with Alzheimer's Disease, Parkinson's Disease and Huntington's Disease.³¹ The average age of the contraction of CJD is 65 years,³² and symptoms include memory loss and confusion, progressive dementia, loss of coordination, involuntary movements, blindness and loss of speech.³³ Evidence shows that the CJD is fatal within six to 12 months of the onset of symptoms.³⁴

<u>10.3</u> Crossing the species barrier?

In 1959, recognising similarities between two progressive degenerative disorders of the central nervous system, Hadlow identified a connection between scrapie, affecting sheep, and a human TSE, kuru, affecting the Fore natives in the Eastern Highlands of Papua New Guinea.³⁵ Kuru is a form of CJD which was first identified in 1957 when Zigas and Gajdusek recognised that the disease affected approximately ten per cent of the Papua New Guinean tribal population.³⁶ Hadlow subsequently drew parallels between epizootiological, aetiological, clinical, and pathological characteristics of the two diseases,³⁷ and he concluded that the overall resemblance between scrapie and kuru was "too impressive to be ignored."³⁸

A study conducted by Gajdusek and Gibbs in 1972 advanced the argument that, not only were there similarities between scrapie and human TSEs, but that scrapie could be transmitted to primates via oral and intracerebral exposure.³⁹ An explicit link between scrapie and CJD was first made in five years later in October 1977 at an

³¹ Donnelly, C. A. et al (1999) at page 166; Sielder, H. and Malmund, N. 'Creutzfeldt-Jakob's Disease' (1963) 22 Journal of Neuropathology and Experimental Neurology 381-402.

³² Donnelly, C.A. et al (1999) at page 166.

³³ BSE Inquiry (2000) Volume 2, Chapter 2, pages 24-25, at section 2.21.

³⁴ Ibid.

³⁵ Hadlow, W. J. 'Scrapie and Kuru' (1959) 274(7097) The Lancet 289-290, at page 289.

³⁶ See Zigas, V. and Gajdusek, D. 'Kuru: Clinical Study of a New Syndrome Resembling Paralysis Agitans in Natives of the Eastern Highlands of Australian New Guinea' (1957) 2 Medical Journal of Australia 745-54.

³⁷ Hadlow, W. J. (1959) at page 290.

³⁸ Ibid.

³⁹ See Gajdusek, D. C. and Gibbs, C. 'Transmission of Kuru from Man to Rhesus Monkey (Macaca Mulatta) Eight-and-a-Half Years after Inoculation' (1972) 240 *Nature* 351; Gajdusek, D. C. *et al* 'Experimental Transmission of a Kuru-like Syndrome to Chimpanzees' (1966) 209 *Nature* 794-6.

Agricultural Research Council meeting, chaired by the Hon. J. J. Astor.⁴⁰ The Council concluded that the epidemiology of scrapie *could* be related to man, raising the question of the safety of those working with sheep.⁴¹ Concerns were also raised about the public reaction to news of potential risk between infected sheep and a threat to human health. The British sheep export industry at the time was worth an estimated £100 million per annum, and there was consensus that disclosure of a potential risk could place the industry "in considerable jeopardy".⁴²

Results presented at a Medical Research Council meeting held in March 1978, chaired by Professor Walton, showed that there was no evidence that anyone working with scrapie diseased animals had developed CJD,⁴³ and Council members concluded that existing mortality data was "likely to be inaccurate".⁴⁴ However, it is worth noting that the Council observed that the epidemiology of CJD was "poorly understood"⁴⁵ and that a connection between scrapie and CJD could not be ruled out entirely before there was concrete evidence that scrapie did not pose a threat to humans.⁴⁶

10.4 MAFF and the regulation of animal disease in the late 1970s

It is unsurprising that, in the light of the heightened focus on the unknown impact of scrapie, the Ministry of Agriculture, Fisheries and Food (MAFF) became increasingly concerned about risks posed by the transmission of zoonoses through use of infected animal carcasses in animal feed. In 1978, the Labour administration introduced proposals for the drafting of secondary legislation, pursuant to the Disease of Animals Act 1950 to impose controls on rendering process to provide protection against food-borne diseases such as salmonella. The proposed Protein Processing Order required that domestic rendering plants were regulated by licensing system – the granting of a license being subject to the rendering process being capable of destroying particular

⁴⁰ Agricultural Research Council Report of Advisory Committee on Scrapie Research, Meeting of the Council 11 October 1977, YB77/10.11/1.1-1.4.

⁴¹ *Ibid.* at section 1.3.

⁴² *Ibid.* at section 1.4.

⁴³ YB78/3.9/1.1-1.5, at 1.3.

⁴⁴ Ibid.

⁴⁵ *Ibid.* at 1.4.

⁴⁶ *Ibid*.

disease organisms. A Joint Consultation Paper produced by MAFF, the Department of Agriculture and Fisheries for Scotland, and the Welsh Office Agriculture Department, explained that the Order was a necessary and long-awaited response to the growing concern about the increasing incidence of salmonella infection in livestock and poultry, and food poisoning in human beings caused by the contamination of animal protein. It claimed that there was 'strong evidence' to suggest that a 'uniformly high standard of hygiene' in the protein processing industry would significantly reduce the spread of infection.⁴⁷

The 1978 licensing proposals were abandoned by the newly elected Conservative Government in favour of a far less radical approach⁴⁸ of prescribing and enforcing observance of animal feed standards.⁴⁹ According to the Phillips Inquiry, the rendering industry at that time was "virtually unregulated in terms of quality control and production methods".⁵⁰ The Diseases of Animals (Protein Processing) Order 1981, pursuant to the Diseases of Animals Act 1950, was directed primarily at controlling salmonella and similar organisms in meat and bone meal. It was based on a regime of testing animal feed for salmonella as an indicator of the efficacy of the rendering process, giving an 'authorised officer' powers to enter any premises which he had reasonable grounds for believing were being used for the purpose of processing animal protein. In relation to eh implementation of the Order, the Secretary of State for Wales noted that:-

"[i]f you had a negative for salmonella, then the Ministry went away quite happily for six months".⁵¹

It is often argued that these changes in rendering practice were symptomatic the deregulation principles of Thatcher's administration. Winter suggests that the changes might be more suitably attributed to shifts in market patterns and health

⁴⁷ Joint Consultation Paper by the Ministry of Agriculture, Fisheries and Food, the Department of Agriculture and Fisheries for Scotland and the Welsh Office Agricultural Department April 1978 'Protein Processing', YB 78/04.00/1.1-1.25 at 1.1-1.2.

⁴⁸ MAFF Annual Report of the Agricultural Development and Advisory Service (MAFF, HMSO; London; 1980) at pages 9-10.

⁴⁹ The Diseases of Animals (Protein Processing) Order 1981 SI 1981 No.676 (subsequently updated by SI 1989 No.661; Winter, M. (1996) at page 551.

⁵⁰ BSE Inquiry (2000) Volume 13, paragraph 6.51.

⁵¹ Transcript number 19, at page 27.

concerns.⁵² Although this thesis is not charged with determining the grounds for deregulation, it is interesting, from a legal perspective, to observe a pattern of deregulation immediately prior to the identification of BSE in contrast to a phase of *re*-regulation in response to the bovine disease.

It is now widely accepted that the relaxation of rendering controls is the most likely explanation for the transmission of BSE to humans.⁵³ The rendering process relies on the use of solvents to remove fat, followed by heat treatment to remove solvents. During the 1970s, the market for fat products declined, and concerns were raised about the carcinogenic properties of residual solvents and that the health risks created by the heat treatment processes. In response, the temperature at which rendering occurred was significantly reduced in the early 1980s. It is argued that infective agents associated with scrapie and BSE are able to survive heat processing, leading to the introduction of infected animal proteins used in animal feed.

10.5 The marginalisation of uncertainty: defining the potential implications of **BSE** using the rhetoric of risk

Without doubt, one of the most interesting aspects of the BSE episode is the way in which scientific uncertainty in respect of the transmissibility of BSE to humans was marginalised at an institutional level. The term 'institutional' is used here in two different senses – first, to describe institution of science, encompassing its conventional methods of inquiry and analysis, and furthermore, its precepts of rationality, certitude and, objectivity; and second, in relation to the institution of Government, its Departments and Ministries, and the system of Government administration within which Ministers and their civil servants operate. Although the political administration of the epidemic and the scientific analyses underpinning the response were necessarily interrelated components in the collective response to BSE, and to that end ought to be dealt with as being tantamount to each other, the distinction is useful because it allows for an unprecedented consideration of the way

⁵² Winter, M. (1996) at page 551.

⁵³ Ibid.

in which notions of uncertainty and risk were dealt with in specific political and scientific contexts.

The following section draws upon two theories emerging from the BSE crisis – the first portrays the marginalisation of scientific uncertainty; and the second exposes the construction of an ascertained risk notwithstanding pervasive uncertainty – although it is important to recognise that both theories are two sides of the same coin. The practice of marginalising scientific uncertainty necessarily implies that greater value is ascribed to the prospect of being able to define the future as an unambiguous expression of risk than to acknowledging that the future is an unknowable and uncontrollable entity. Conversely, the process by which prospective hazards are defined as fixed and foreseeable risks is a manifestation of the argument that all eventualities can be articulated in quantitatively certain terms, and, more importantly, that the notion of scientific uncertainty can be circumvented by specific measures of risk. To the extent that scientific risk assessment is able to calculate the likelihood and potential magnitude of forthcoming hazards, the notion of uncertainty is marginal.

Using as a framework the institutional distinction between the political and the scientific handling of BSE, outlined above, this chapter draws attention to both aspects of uncertainty and risk. It is split into two parts. The first examines scientific assessments undertaken in relation to the threat of BSE. It observes that, in accordance with the consensus of the scientific community, it was widely accepted that BSE was a strain of bovine scrapie. With reference to Kuhn's notion of the 'scientific paradigm', it shows that science-based risk assessments reflected a consensus amongst Government scientists that both the likelihood of the transmission of BSE to humans, and the subsequent threat of adverse consequences, were negligible. From this perspective, and applying Kuhn's thesis of scientific revolution, it can be said that the findings of scientific risk assessment mirrored the 'paradigmatic consensus'. However, the validity of this paradigmatic consensus depended entirely on the legitimacy of the comparison drawn between BSE in cattle and scrapie in sheep. It is clear that assessments of the risk posed to human health by BSE were based firmly on the position that BSE and scrapie were analogous diseases. Yet, as this chapter illustrates, the knowledge upon which risk assessments in relation to BSE were based lacked both in applicability and comprehensiveness. Even though information about the nature of the BSE agent was deficient - making it impossible to come to any definite conclusions about its capacity to infect humans - the threat of human transmission was nonetheless constructed in definite terms as a risk, as opposed to *uncertainty*. The root of the problem is explained through a more general The fundamental issue here is the critique of conventional risk assessment. dependence of risk assessment procedures on existing evidence obtained from observations of a broadly similar event. Under the heading 'Asking the Wrong Questions', this section illustrates that the backward-looking nature of risk assessment models is profoundly incompatible with the forward-looking character of anticipatory regulation. Whilst declarations that there was no evidence of human susceptibility to BSE were factually accurate, they were improperly used as a means of bestowing scientific legitimacy upon predictions that the risk of transmission was either nonexistent, or low. Thus, whilst the scrapie analogy was an effective vehicle allowing for definite expressions of risk on the ground that there was no evidence of human infection, it was nonetheless meaningless as a way of predicting the unknown impact of BSE.

The second part of this chapter focuses on the marginalisation of uncertainty and construction of risk in the political administration of the BSE episode. In doing so, it points to the communication of risk, both within Government departments and between the Government and the public. Under the heading 'Reassurances of Safety', it is shown that Government officials were improperly selective in their interpretation of scientific advice. This section presents a sample of internal and external dialogue regarding the threat of BSE to illustrate that, in spite of that fact that scientific studies often conceded that it might take a number of years until the real impact of BSE could be measured, the Government maintained its dogmatic stance that British beef was safe to eat. Irrespective of growing concern expressed by independent scientists and the media that models assessing the human implications of BSE should be taken as having wide margins of confidence, the Government continued to have uttermost faith in scientific analyses, placing scientifically-certain evidence at the core of its policy and legislative initiatives. Two explanations are presented in an attempt to account for this political marginalisation of uncertainty. First, relating specifically to the functions of MAFF, it is argued that the Government acted so as to protect the commercial interests of the agricultural export industry. Second, and on a more general note, the prospect of decisions being subject to judicial review is manifestly incompatible with the notion of 'scientific *uncertainty'* – thus cultivating the practice of demanding scientific certainty before decisions are made.

This combination of the scientific and political understanding of BSE resulted in the threat of transmissibility to humans being presented as a *known* risk, albeit a *remote* one. In effect, both scientific and political interpretations of the potential implications of BSE were framed in such a way that scientific uncertainty became a peripheral matter. This chapter refers to the tangential treatment of uncertainty as 'the *marginalisation* of uncertainty'.

10.6 The marginalisation of uncertainty in scientific assessment: the 'scrapie origin theory'

In scientific analyses of the transmissibility of the BSE agent, models used to predict patterns of infectivity, susceptibility, and transmission routes were based wholly on retrospective studies of scrapie. From the outset, a pathological analogy was drawn between BSE and scrapie. The BSE Inquiry explained that, "[a]s scrapie in sheep and goats was the only TSE known to affect farm animals in the UK, it was the main candidate for the source of the epidemic in cattle."⁵⁴ The results of an initial epidemiological investigation, published in the *Veterinary Record* in December 1988, concluded that it was most likely that BSE derived from existing strains of scrapie.⁵⁵ It found that, although there was no evidence to suggest that direct transmission occurred between sheep and cattle, exposure to the scrapie agent through sheep offal in cattle feedstuffs was the probable cause of infection. Furthermore, it recognised that, given that cattle had only become infected with BSE *after* changes in the rendering process, rendering had failed to inactivate scrapie. The conclusion was drawn that cattle had always been susceptible to the scrapie agent, although in the

⁵⁴ BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.16.

⁵⁵ Wilesmith, J. et al 'Bovine Spongiform Encephalopathy: Epidemiological Studies' (1988) 123 Veterinary Record 638-44.

past, their exposure to it had been insufficient to cause any noticeable incidence of disease.⁵⁶

The views expressed by experts in the late 1980s and early 1990s were steadfast in their commitment to the theory that scrapie and BSE were essentially the same strain of TSE. The prevailing opinion was that BSE was simply 'scrapie in cows',⁵⁷ or 'bovine scrapie'⁵⁸ and that, given their similarities, "BSE and scrapie should be treated as one and the same for safety purposes."⁵⁹ Indeed, the analogy dominated analyses of the potential threat posed to human health by the BSE agent. The process of determining both the likelihood that humans were susceptible to BSE, and the magnitude with which human transmission was likely to occur, were based on risk models assessing the infectivity of scrapie. A minute sent to the Director of the Central Veterinary Laboratory (CVL) by the Head of the CVL Pathology Department is perhaps the most concrete indication that scrapie patterns were pivotal in the forming of early insights into the behaviour of BSE (see figure 2, below).

John Wilesmith, Head of Epidemiology at the CVL, suggested that a number of factors contributed to the outbreak of BSE epidemic, collectively pointing to scrapie as the most likely cause of BSE.⁶⁰ These included the dramatic increase in the sheep population in Great Britain; a probable, but unproven, increase in the prevalence of scrapie-infected flocks; a greater inclusion of sheep heads and of casualty sheep in material for rendering; the introduction of continuous rendering processes during the 1970s and 1980s; and, the decline in the practice of using solvent extraction of tallow in rendering since the mid-1970s. According to Wilesmith, the pivotal factor in the development of BSE was the establishment of continuous rendering processes that might have led to the rendering of animal material at lower temperatures or for shorter periods, resulting in the failure to destroy the scrapie agent.⁶¹

⁵⁶ Wilesmith, J. et al 'Bovine Spongiform Encephalopathy: Epidemiological Studies on the Origin' (1991) 128 Veterinary Record 199-203.

⁵⁷ BSE Inquiry (2000) Volume 1, at paragraph 711; for further descriptions of analogy between BSE and scrapie, see YB87/6.10/4.1 and YB87.6.04/1.1.

⁵⁸ YB86/12.19/1.1.

⁵⁹ YB88/12.07/7.2.

⁶⁰ Wilesmith, J. et al (1988); see also BSE Inquiry (2000) Volume 2, paragraph 3.22.

⁶¹ BSE Inquiry (2000) Volume 2, at paragraph 3.23.



Figure 2. YB88/12.8/3.1.

The rendering industry processed waste from the carcasses of cattle, crushing the raw material and indirectly applying heat. The evaporation of moisture separated the fat, known as 'tallow', from the high-protein solids, known as 'greaves'. The greaves were pressed, centrifuged, or subjected to solvent extraction to get rid of more tallow, before being ground into meat and bone meal (MBM). Although tallow was the primary product of rendering, both tallow and MBM had good commercial value in the 1980s.⁶² Depending on its quality, tallow was used for direct human consumption, or the manufacture of soap or industrial lubricant, and MBM was used largely in animal feed.

Wilesmith suggested that compound animal feed containing infective MBM was the principal means by which BSE developed and spread throughout the UK. He concluded that changes in the rendering process probably brought about the emergence of the bovine disease. The continuous rendering method was introduced

⁶² *Ibid.* Volume 13, at paragraph6.1.

in the 1960s, replacing the less efficient 'batch processing' (see figure 2).⁶³ Most rendering plants had previously used 'dry rendering', or 'atmospheric' batch processing systems.⁶⁴ Before being cooked, raw material was fed into a crusher, breaking up the fatty and gut tissue before transferring the mass into a cooker. The cooker was heated at a normal atmospheric pressure to approximately 100°C so that moisture was removed in the form of steam through vents. The temperature was then increased to 140°C or more, causing the cell structure of the residue to break down, releasing the fat as tallow. The tallow was then removed into a separate vessel and the remaining solids emptied from the cooker.

Continuous systems used heating, separation, and cooling on a continuous flow basis. Raw material was fed in at one end of the cooker, and the product emitted at the other. The treatment was similar to that used in dry rendering batch systems, although it was more automated allowing more accurate control over the crushing process, the temperature and the time of rendering.⁶⁵ Greater automation led to increased flexibility, allowing for a wider range of time and temperature combinations in the cooking of raw material. Whereas some continuous systems operated between 104 to 145°C for a period of between fifteen minutes and two and half hours,⁶⁶ others only heated material for three to seven minutes at about 95°.⁶⁷



Figure 3. Proportion of MBM produced by plants using a continuous rendering process, 1971-88.⁶⁸

⁶³ *Ibid.* at paragraph 6.6.

⁶⁴ Ibid. Volume 13, Annex B, at paragraph 6.80.

⁶⁵ *Ibid.* Volume 13, at paragraph 6.82.

⁶⁶ For example, 'Stork Duke', 'Stord Bartz', and 'Carver-Greenfield' continuous rendering systems. See BSE Inquiry (2000) Volume 13, at paragraph 6.92.

⁶⁷ For example, 'Protec' rendering systems. See BSE Inquiry (2000) Volume 13, at paragraph 6.92.
⁶⁸ Wilesmith, W. J. *et al* (1991) at page 201.

A Senior Scientific Officer from the Veterinary Investigation Centre at Preston, observed that the cooking times and temperatures were poorly recorded, inaccurate, and failed to reach the degree necessary to destroy the scrapie agent which was known to survive temperatures of 136°C for 18 minutes.⁶⁹ In a draft report on the 'Rendering Industry and BSE' produced in April 1988,⁷⁰ he concluded that:-

"[t]he rendering industry operates with processes which with few exceptions are inadequate to destroy scrapie agent. This together with increasing amounts of sheep material consisting of whole carcasses and heads which undoubtedly contain increasing numbers of scrapie cases may have resulted in contaminated tallow and meat and bone meal reaching the animal feed compound industry.

Scrapie contaminated material has probably always entered and survived the rendering process but only in small amounts prior to 1980. With the change to continuous rendering large volumes of contaminated products have been introduced to the food chain."⁷¹

The finding that the infectious scrapie agent had been introduced via commercial cattle feedstuffs stemmed from the absence of any direct epidemiological evidence of other sources of the agent, together with the fact that BSE was a common source epidemic. This theory that BSE had a scrapie origin was critical in prompting claims that BSE and scrapie were directly comparable. Commenting on the findings of the Southwood Working Party Report, Sir Richard Southwood concluded that "[t]here were good grounds for assuming that the likelihood that BSE was like scrapie was high."⁷² Following the initial identification of BSE, it was accepted that it was pathologically comparable with scrapie. In a minute recording the identification of neuronal vacuolation in a bovine brain, the head of the Pathology Department noted that "the lesions observed have similarities to spongiform encephalopathies of other species and in particular scrapie of sheep."⁷³

⁶⁹ S45 Smith, at paragraph 2.

⁷⁰ YB88/4.27/5.1-5.6.

⁷¹ YB88/4.27/5.3.

⁷² Witness statement 483, at paragraph E16.

⁷³ YB86/12.19/1.1.

Likewise, following the initial pathological examination of Cow 142, a senior pathologist at the CVL, Carol Richardson, claimed that although she had never seen the combination of neuronal and neuropil vacuolation before in a cow, she had frequently observed it in scrapie-infected sheep.⁷⁴ Despite the fact that pathological observations made in December 1986 only lent themselves to a provisional diagnosis, Richardson recalled that, at the time, she was certain that the bovine brain samples confirmed the existence of scrapie-associated fibrils cattle.⁷⁵ By August 1987, Dr Wells, head of the Consultant Pathology Unit at the CVL, was adamant that "[n]ow with even more confidence than formerly we can draw similarities with scrapie of sheep and I feel that scientifically this cannot be avoided."⁷⁶

The overriding view was that, because BSE bore such close similarities to scrapie, and because scrapie had existed for centuries prior to the identification of BSE and had not been known to pose any threat to human health, it was similarly unlikely that BSE would cause any ill health to humans. A study, published in 1987, observed that scrapie had never infected humans in spite of opportunities to do so during the 250 years in which the disease had contaminated sheep meat products entering the human food chain.⁷⁷

Yet, despite the prevailing opinion, a small number of experts were deeply sceptical from the outset of the appropriateness of the scrapie analogy. Adopting a stance critical of the comparison drawn between scrapie and its suspected counterpart in cows, Professor Richard Lacey⁷⁸ and Stephen Dealler⁷⁹ claimed that evidence confirming the scrapie-BSE analogy was 'nonexistent', and as a result felt they could not assert, with any degree of confidence, that the BSE agent from bovines would not be infectious for man.⁸⁰ By the same token, John Suich,⁸¹ in his correspondence with the British Embassy in The Hague, wrote that "there is no evidence that BSE is

⁷⁴ S69 Richardson, at paragraph 12.

⁷⁵ Ibid.

⁷⁶ YB87/8.4/2.1.

⁷⁷ Brown, P. *et al* 'The Epidemiology of Creutzfeldt-Jakob Disease: Conclusion of a 15-Year-Investigation in France and Review of the World Literature' (1987) 37 *Neurology* 895-904.

⁷⁸ Emeritus Professor of Clinical Microbiology, University of Leeds.

⁷⁹ Public Health Laboratory Service.

⁸⁰ IBD1 tab 7 at page 19-20.

⁸¹ MAFF, Animal Health Division.

attributable to the same cause as scrapie and it is important to distinguish between the two conditions".⁸²

Indeed, the discord amongst experts in relation to the utility of the scrapie analogy might be described as an illustration of the Kuhnian model of paradigmatic revolution. It is clear that, for the most part of the BSE episode, scientific forecasts of the potential health threats posed by BSE reflected the paradigmatic consensus that BSE and scrapie were directly comparable.⁸³ That is, until the early 1990s when there was a paradigmatic shift brought about mounting recognition that scrapie and BSE were dissimilar diseases. However, prior to this disciplinary recognition of their distinct pathological and epidemiological properties, assessment procedures used as a means of determining the risk of the transmission of BSE to humans depended entirely on existing epidemiological knowledge about the scrapie agent. Given the novelty with which BSE presented itself, information about its infectivity, routes of exposure, and the effect of the species barrier was clearly incomplete. Consequently, models tracing the behaviour of the scrapie agent based on previously conducted investigations were projected into the future so as to predict patterns of the transmissibility of BSE. The scientific assessment upon which assurances of the safety of BSE-infected material reflected quantitative data on the pathogenic characteristics of the scrapie agent. The risk of transmission of BSE to humans was understood as being contingent on the dose of infected material required to bring about the onset of BSE – otherwise known as the 'effective dose'⁸⁴ – which was itself considered to be a function of three factors - the infectivity titre of the contaminated material; the route of exposure; and, the species barrier effect.⁸⁵

⁸² YB87/10.30/1.1.

⁸³ BSE Inquiry (2000) Volume 2, at paragraph 3.61.

⁸⁴ See BSE Inquiry (2000) Volume 2, at paragraphs 3.126, 3.163, and 3.180.

⁸⁵ Annex A to Witness Statement 147C, Mr Colin Maclean.

10.7 Effective dose assessments

<u>10.7.1 Infectivity titre</u>

Determining the infectivity titre of BSE was crucial to the introduction of the SBO ban on 13 November 1989.⁸⁶ In the absence of an infectivity test for BSE, and before results of infectivity tests were available for BSE, the process of ascertaining which cattle tissues carried the BSE agent was governed by studies undertaken in relation to scrapie. In a written statement, Professor Southwood confirmed that:-

"[t]here was no, or virtually no scientific knowledge concerning BSE available at this time. We worked on the basis that scrapie was the most likely cause of the BSE epidemic; we had to base our advice on the science relating to scrapie at that time".⁸⁷

Investigations into the nature of scrapie conducted by Hadlow *et al* in 1980⁸⁸ and 1982⁸⁹ found that the greatest concentration of disease occurred in the brain and spinal cord of sheep (see figure 3, below). Given the absence of data relating to the infectivity of BSE to humans, the decision by MAFF to prohibit the use in human food of types of offal most likely to have a high infectivity titre of BSE was scientifically underpinned by the outcome of the *Hadlow* investigations. Announced on 13 June 1989, and brought into force five months later, the human SBO ban was established pursuant to the Food Act 1984, and made use of mechanisms already in place under the Meat (Sterilisation and Staining) Regulations 1982 designed to deal with unfit meat. Reflecting the categorisation of scrapie infectivity, the SBO measure applied only to the use of 'high risk' tissues – such as the brain, spinal cord, spleen and tonsils.⁹⁰ It is important to note that it did not prohibit the use of tripe and rennet, both extracted from the abomasum; mesenteric fat, taken from the intestine; offal from calves aged less than six months; and, mechanically recovered meat deriving

⁸⁶ BSE Inquiry (2000) Volume 2, at paragraph 3.60.

⁸⁷ S483 Southwood, at paragraph 42.

⁸⁸ Hadlow, W. J. et al 'Virologic and Neurohistologic Findings in Dairy Goats Affected with Natural Scrapie' (1980) 17 Veterinary Pathology 187-189.

⁸⁹ Hadlow, W. J. et al 'Natural Infection of Suffolk Sheep with Scrapie Virus' (1982) 146 Journal of Infectious Disease 657-664.

⁹⁰ The Bovine Offal (Prohibition) Order 1989, section 2.

from the spinal column. It was widely accepted that preventing only tissues with the *highest* concentration of infectivity was itself a 'measure of extreme prudence',⁹¹ and that the combination of low infectivity, together with ineffective routes of exposure and the species barrier rendered any further precautions relating to other bovine tissues wholly unnecessary.

10.7.2 Routes of exposure and the species barrier

Knowledge about potential routes of exposure and the effectiveness of the species barrier was also limited to data drawn from parallel investigations analysing the behaviour of either scrapie, or BSE in infected mice. Studies into routes of exposure found that oral or intragastric infection of scrapie was between 50,000 to 100,000 times less efficient than the intracerebral route of infection.⁹² Large oral doses of high titre scrapie-infected tissue led to the assumption that the oral route of transmission of scrapie was very inefficient.⁹³ Furthermore, models assessing the effectiveness of the species barrier in limiting the transmission of BSE suggested that the species barrier between cattle and mice would reduce effective exposure by 1,000 fold.⁹⁴ Despite the fact that evidence in relation to both likely routes of exposure and the significance of the species barrier in *humans* was absent, it was assumed that patterns of cattle to human transmission would mirror these findings. On this basis, experts advising MAFF concluded that it was extremely unlikely that the human consumption of BSEinfected offal would present any threat to human health because effective exposure was inhibited not only by the inefficiency of the oral route of infection, but also by the species barrier resisting the transmission of BSE from cattle to humans.

⁹¹ YB89/2.21/2.4

⁹² Kimberlin, R. and Walker, C. 'Pathogenesis of Scrapie in Mice after Intragastric Infection' (1989) 12 Virus Research 213-220; Diringer, H. et al 'The Nature of the Scrapie Agent: The Virus Theory' (1994) 724 Annals of the New York Academy of Science 246-258.

⁹³ BSE Inquiry (2000) Volume 2, at paragraph3.191.

⁹⁴ Bruce, M. et al 'Transmission of Bovine Spongiform Encephalopathy and Scrapie to Mice - Strain Variation and the Species Barrier' (1994) 343 Phil. Trans. R. Soc. Lond. B 405-411.

Category	Titre (log10/30mg)	Tissues
i	3.9-4.1	Brain, spinal cord.
ii	2.7-3.2	Lymph nodes, Peyer's patches, spleen, tonsil, proximal colon.
iii	0.8-1.6	Pituitary, sciatic nerve, adrenal, distal colon.
iv	<0.8	Blood, bone marrow, CSF, heart, kidney, lung, gonads, mammary gland, thymus, thyroid, uterus, salivary gland, muscle, milk, serum, faeces, saliva.

Figure 4. Categorisation of the relative infectivity of sheep and goat tissue based on data derived from Hadlow *et al* 1980 and 1982.

10.8 Deficiencies in risk assessment

The BSE Inquiry acknowledged that almost every decision regarding BSE had to be made when uncertainty about its capacity to affect human health was endemic,95 noting that "[d]oing nothing until firm information was available was itself risky, because answers to such questions might not [have] become available for years."96 The potential latency of human implications meant that decision-making was not only urgent, but had to be based on information available at the time, albeit incomplete. The pressing need for immediate decisions about the inclusion of infected cattle in the human food chain meant that the risk assessment process became a key tool in the formulating of BSE policy. The feeling amongst experts was that a formal risk assessment procedure was the only logical basis for introducing control measures.⁹⁷ In particular, Richard Kimberlin⁹⁸ was of the opinion that, irrespective of the fact that comparisons drawn between scrapie and BSE were only tentative, it was crucial that decision-making was founded on some scientific measurement. Commenting on the question of human transmissibility, he claimed that "these issues can only be understood in the context of risk assessment, which I regard as an essential tool for making rational decisions."99

Yet, whilst disciplinary support for conventional models of risk assessment was construed as evidence of the accuracy of their predictions, the categorical acceptance of findings of 'remote risk' failed to take into account the fact that the results bore no

⁹⁵ BSE Inquiry (2000) Volume 15, Chapter 5, at paragraph5.3.

⁹⁶ Ibid.

⁹⁷ Witness Statement 179, at paragraph 112.

⁹⁸ TSE research scientist at the Neuropathogenesis Unit, Edinburgh.

⁹⁹ Witness Statement 95C, at paragraph 21.

meaning in relation to BSE. Their significance was restricted to reflecting preceding observations of either the nature of scrapie or the epidemiological patterns of BSE in infected mice. And, in that sense, their usefulness was limited to providing an account of the past, as opposed to the future.

The fundamental problem in any risk assessment for BSE was that there was no firm information on the nature of the disease. Having observed the significance explicitly attributed to formal processes of risk assessment during the BSE episode, it is interesting to consider the disparity between deficiencies in knowledge about BSE and the tradition of risk assessment to extrapolate future predictions from evidence of past events. To some extent, the predicament was encapsulated by Jack Done of the CVL when he stated that "[i]t is, of course, fallacious to maintain that modelling can only be of any use when it uses 'robust' assumptions."¹⁰⁰ Without any concrete understanding of the epidemiology of BSE, and given that, typically, risk assessment models are inherently evidence-based decision-making tools, it was inevitable that the paucity of available information would be compensated for by forecasts reflecting pre-existing knowledge about the nature and behaviour of scrapie in sheep. In other words, whilst it was impossible to formulate an assessment of risk based on direct observations of the human consumption of BSE-infected tissue, predictions were nonetheless perceived as being relevant because of the theory that cases of BSE were index cases of cattle infected with scrapie.

Of course, the utility of this practice of projecting the past into the future is contingent on the factual similarity between the past and the future. As will be seen, this similarity was more idealistic than realistic – the upshot being that ensuing risk assessments could not accurately apply to the BSE problem. This section exposes the critical problem that, although the scrapie analogy was pivotal in the regulation of BSE, it subsequently proved to be fallacious. From as early as 1988, there was evidence to suggest that BSE and scrapie were markedly different in three senses – in terms of their host range, transmission properties, and pathogenesis¹⁰¹ – although this was not recognised by mainstream scientific opinion until it had been established that BSE was the most likely cause of human CJD.

¹⁰⁰ YB91/4.06/1.1.

¹⁰¹ BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.49.

10.8.1 Host range

A substantial body of evidence shows that the range of species (the 'host range') susceptible to BSE is markedly different to the range susceptible to scrapie. In 1987 and 1988, experimental studies found that BSE could not be transmitted to hamsters intracerebrally inoculated with BSE-infected material,¹⁰² despite the fact that studies had already confirmed that hamsters were readily susceptible to the scrapie disease. Conversely, investigations established that BSE could be transmitted to a wide range of hosts which had not been shown to be receptive to scrapie. Examples include the successful experimental transmission of BSE through intracerebral, intravenous, intraperitoneal, or oral means to pigs;¹⁰³ mink;¹⁰⁴ several exotic ungulates, including nyala,¹⁰⁵ gemsbok,¹⁰⁶ Arabian oryx,¹⁰⁷ greater kudu,¹⁰⁸ eland,¹⁰⁹ moufflon,¹¹⁰ and scimitar horned oryx;¹¹¹ and exotic carnivores, such as puma,¹¹² cheetah,¹¹³ and ocelot.114 The appearance of BSE in domestic and wild cats was a crucial development in the comparison drawn between BSE and scrapie.¹¹⁵ It illustrated that it was no longer plausible to claim that BSE was merely scrapie in cows with the

¹¹⁰ Bradley, R. 'Animal Prion Diseases', in Collinge, J. and Palmer, M. S. (eds) Prion Diseases (Oxford University Press; Oxford; 1997) at page 89, as cited in the BSE Inquiry (2000) ibid.

¹⁰² See YB87/6.9/1.3 and YB88/3.00/1.6.

¹⁰³ M40 tab 4.1.

¹⁰⁴ Robinson, M. et al 'Experimental Infection of Mink with Bovine Spongiform Encephalopathy (1994) 75 Journal of General Virology 2151-5, as cited in the BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.51. ¹⁰⁵ Jeffrey, M. and Wells, G. 'Spongiform Encephalopathy in Nyala (Tragelaphus Angasi)' (1988) 25

Veterinary Pathology 398-9, as cited in the BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.52.

¹⁰⁶ Kirkwood, J. and Cunningham, A. 'Epidemiological Observations on Spongiform Encephalopathies in Captive Wild Animals in the British Isles' (1994) 135 Veterinary Record 296-303, as cited in BSE Inquiry (2000) ibid.

¹⁰⁷*Ibid*.

¹⁰⁸ *Ibid*. ¹⁰⁹ Ibid.

¹¹¹ *Ibid*.

¹¹² Willoughby, K. et al 'Spongiform Encephalopathy in a Captive Puma (Felis Concolor)' (1992) 131 Veterinary Record 431-4, as cited in the BSE Inquiry (2000) ibid.

¹¹³ Peet, R. and Curran, J. 'Spongiform Encephalopathy in an Imported Cheetah (Acinox Jubatus)' (1992) 69 Australian Veterinary Record 171, as cited in BSE Inquiry (2000) ibid.

¹¹⁴ Johnson, R. and Gibbs, C. 'Creutzfeldt-Jakob Disease and Related Transmissible Spongiform Encephalopathies' (1998) 339 New England Journal of Medicine 1944-2004, as cited in the BSE Inquiry (2000) ibid.

¹¹⁵ Wyatt, J. et al 'Spongiform Encephalopathy in a Cat' (1990) 126 Veterinary Record 513, as cited in BSE Inquiry (2000) ibid.; see also YB98/0.0/1.1; and, Amyx, H. et al 'Experimental Creutzfeldt-Jakob Disease in Cats', in Court, L.A. and Cathala, F. (eds) Unconventional Viruses and the Central Nervous System (Masson; Paris; 1983) 358 – a study failing to experimentally transmit two different strains of scrapie to cats - cited in the BSE Inquiry (2000) ibid.

same properties, and that the BSE agent possessed very different biological properties to scrapie, manifesting themselves in the extended host range of affected species.¹¹⁶

<u>10.8.2 Transmissibility</u>

In addition to models tracing the respective host ranges of BSE and scrapie, studies into the transmissibility properties of both agents found that their incubation periods differed to such an extent that the diseases could not be compared.¹¹⁷ Experiments confirmed that both mice and marmosets incubated BSE for a longer period than scrapie.¹¹⁸ After having been experimentally inoculated in February 1988, marmosets succumbed to scrapie between two to eight months earlier than those animals inoculated with BSE. A summary of an informal SEAC meeting recorded that the separation between incubation periods was 'striking'.¹¹⁹

The transmission properties of BSE and scrapie also differed in the pattern of disease recorded in the brains of experimental animals. Whereas mice inoculated with scrapie-infected material from geographically and temporally distinct sources had variable brain lesions, mice inoculated in the same way with BSE-infected material displayed very similar patterns of disease. Not only did the studies show that the lesion profile produced by BSE was different to that produced by scrapie, but also that, unlike scrapie, only one strain of BSE was present in inocula derived from geographically and temporally distinct sources.¹²⁰

This distinction merely confirmed the outcome of a previously conducted investigation that BSE and scrapie did not develop from the same source. Although an experiment to determine whether the two diseases were derivatives of the same

¹¹⁶ Transcript number 94, at pages 75-6.

¹¹⁷ S65 Wells, at paragraph 47.

¹¹⁸ YB92/2.27/3.1-3.5.

¹¹⁹ Ibid.

¹²⁰ Bruce, M. *et al* 'Transmissions to Mice Indicate that "New Variant" CJD is Caused by the BSE Agent' (1997) 389 *Nature* 498-501, as cited in BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.56.

agent was never undertaken in the UK, a study performed in the USA in 1979 showed that cattle inoculated with the scrapie agent developed a TSE quite unlike BSE.¹²¹

• <u>10.8.3 Pathogenesis</u>

Similar pathogenesis studies designed to observe the manner in which both BSE and scrapie developed also revealed that, although BSE is a 'scrapie-like' disease, its characteristics were very different once it emerged in cattle.¹²² The Phillips Inquiry concluded that, although the "pathological *similarity* to scrapie was a fact",¹²³ it was not proof that BSE was merely a strain of scrapie in cows. Dr Kimberlin supported this viewpoint, stating that:-

"[t]here definitely was some good scientific data that said that sometimes, when you cross a species barrier, you create a situation in which the agent will change. You actually exercise or impose a selective pressure, the consequence of which is that the agent can change. So the ethos of scrapie not being transmissible to man that we knew about, and BSE probably having a scrapie origin, did give grounds for optimism, but by itself, it really was not enough to say that there would be no problem from BSE."¹²⁴

Yet, in spite of the fact that it was clear that BSE and scrapie were not directly comparable, the scrapie analogy continued to govern the regulation of BSE throughout the episode until MAFF acknowledged in 1996 that the BSE agent might be transmittable to humans.

¹²¹ See Clark, W. *et al* 'Encephalopathy in Cattle Experimentally Infected with the Scrapie Agent' (1995) 56 *American Journal of Veterinary Research* 606-612, as cited in BSE Inquiry (2000) Volume 2, Chapter 3, at paragraph 3.57.

¹²² BSE Inquiry, Volume 2, at paragraph3.61.

¹²³ *Ibid.* at paragraph 2.188, emphasis added.

¹²⁴ Transcript number 6, at page 50.

10.9 Too many variables

This section points to the shortcomings of conventional risk assessment in the BSE crisis, illustrating that the process was unfeasibly idealistic in its reliance on the linearity and regularity of circumstance, and that this rigidity generated inaccurate and unrealistic calculations of risk. It shows that, regardless of the fact that the scrapie analogy proved to be factually inapplicable, predictions deriving from scientific risk assessment were always going to be limited by the inability of such a model to account for the unforeseen. In other words, the fallibility of the scrapic analogy, and the resultant irrelevance of scrapie models in determining the potential nature of BSE, presented only part of the problem with traditional risk assessment. The other problem lay in its intransigence. Its incapacity to engage with conditions beyond those already taken into consideration for the purpose of prediction limited its utility as a means of meaningful prediction. This inadequacy was particularly well demonstrated by the failure of the risk assessment conducted by the Southwood Working Party to anticipate that the mechanical recovery of meat in practice might not reflect the process envisaged by on paper. This discord between reality as it transpired, and the *construction* of reality prior to its materialisation, inevitably led to the misleading application of risk predictions. That is not to say, however, that the problem of the social construction of reality can ever be resolved. Risk assessment procedures undertaken in anticipation of potential happenings necessarily rely current understandings of the future, thus making the potential inaccuracy of current projections an inescapable weakness of any risk assessment. The argument here focuses not on the precision of risk forecasts - which, by virtue of the nature of any attempted insight into the future, are tarnished by the inability to know or define forthcoming events – but instead on the unyielding rhetoric of risk assessment and its resultant incapacity to acknowledge that its predictions are unconditionally dependent on reality emulating projected constructions of reality.

Naturally, the effectiveness of risk assessment will depend entirely on the information available. Any assessment relying on too many variables is unlikely to ever be a useful tool for action.¹²⁵ This problem arose in relation to the SBO ban and

¹²⁵ Witness statement 78A, at paragraph 11.

mechanically recovered meat (MRM). Once the bulk of meat had been removed from the carcass, a mechanical recovery process applied high pressure to bones to separate any remaining meat for use in a range of meat products for human consumption. The advice of MAFF scientists, which was accepted by the Department of Health, was that it was 'most unlikely' that any BSE agent would be present in MRM.¹²⁶ In a minute recording a meeting to discuss the proposed ban on specified offal, John Maslin of the Animal Health Division recalled the decision that no action should be taken in respect of MRM because it did not present 'a significant risk'.¹²⁷ The Chief Veterinary Officer at the Department of Agriculture, Northern Ireland,¹²⁸ who was present at that meeting, commented that:-

"[w]hat we were trying to do here was try to put what we thought at the time was a fairly small risk and put it into context and draw a line somewhere, do a risk analysis on it and draw a line. And I think the conclusion of the meeting as recorded there was that this was such a small risk it was *completely negligible*, was the conclusion that the time."¹²⁹

The argument that MRM posed only a minimal risk to human health was contingent on the successful removal of spinal cord from the carcass, pursuant to the SBO ban. Furthermore, the legitimacy of the contention that there was an *insignificant* chance of MRM containing BSE was acutely dependent on knowledge of the process of carcasssplitting and removal of spinal cord; knowledge of the process of MRM extraction; knowledge of standards of the operation, inspection, and monitoring of abattoirs; as well as an understanding of what was known, and what was not known, about infective dose in relation to TSEs.¹³⁰ It transpired that this knowledge was in short supply – the upshot being that the application of the SBO ban in relation to bovine spinal cord did not correspond with predictions drawn from risk assessment procedures, resulting in infectious spinal cord tissue entering MRM.

¹²⁸ Deputy Chief Veterinary Officer, Northern Ireland.

¹²⁶ Witness Statement 75C, at paragraph92.

¹²⁷ YB89/9.29/6.1.

¹²⁹ Transcript number 80, at page 131, emphasis added.

¹³⁰ BSE Inquiry (2000) Volume 1, at paragraph 604.

Spinal cord, together with brain tissue, had been identified as having the highest titre of BSE infection.¹³¹ It was a major source of bovine MRM, and, once it was prescribed as an SBO, was prohibited from entering human food under the Bovine Offal (Prohibition) Regulations 1989.¹³² The Phillips Inquiry noted that "[t]here was never any apprehension that, once removed, SBO would find its way into the human food chain."¹³³ However, practical problems in relation to the implementation of the ban developed – largely from incomplete knowledge on the part of regulators about the mechanical meat recovery process. Essentially, the removal of SBO involved cutting the carcass in half along the backbone, and exposing and removing the spinal cord. The process required meticulous skill and care, and Meat Inspectors had to be vigilant in ensuring that carcasses would only receive a health stamp if it did not contain any remnants of spinal cord. It was inevitable that sometimes parts of spinal cord were damaged, remaining trapped or hidden within the vertebrae. As a result, infected tissue would pass undetected into human food chain via MRM.

At the time, the Director of the Environmental Health (Scotland) Unit recognised that the practice of extracting MRM, as anticipated in risk assessment models, was not translated in practice. He claimed that in the aftermath of the implementation of the SBO ban it was not possible to guarantee that parts of the central nervous system of cattle would not enter products intended for human consumption.¹³⁴ He went on to note that "whether or not the practice of producing mechanically recovered meat can be considered safe is very much open to doubt."¹³⁵

10.10 No formal risk assessment

A second criticism of risk analysis during the BSE crisis draws attention to its inherently haphazard structure. Although, by 1988, MAFF had a "well-ordered system for food chemical risk assessment",¹³⁶ policy-makers considering the

¹³¹ Hadlow, W. J. et al (1982).

 ¹³² SI No.2061. See Explanatory Note, which states that the Regulations apply to "the brain, spinal cord, spleen, thymus, tonsils and intestines of bovine animals slaughtered in the United Kingdom."
 ¹³³ BSE Inquiry (2000) Volume 1, at paragraph 615.

¹³⁴ BSE Inquiry (2000) Volume 9, at paragraph 11.36.

¹³⁵ BSE Inquiry (2000) Volume 1, at paragraph 628

¹³⁶ Witness statement 435, at paragraph 19.

implications of BSE had very little guidance in the prediction of its impact on human health.¹³⁷ Traditionally, assessing the likelihood and magnitude of threats posed by chemicals in food made use of an established framework. Mr Dickinson¹³⁸ noted that in the mid-1980s, there were routine methods for assessing the toxicological risks created by food additives, contaminants, and residues. He observed that the broad thrust was to prevent any unnecessary risk in food using decision-making tools such as No Observed Effect Levels, Acceptable or Tolerable Daily Intakes, and Maximum Residue Limits.¹³⁹ However, in spite of the fact that coherent models of risk assessment were well developed by the late 1980s, MAFF officials dealing with the risk of BSE transmission to humans appear to have adopted a rather more arbitrary approach to risk prediction. In the words of Donald Peacock:-

"There is little evidence, however, that a thorough risk assessment was made and too heavy a reliance was placed on known scientific proof when all along we realised that there was a great deal that was (and I still believe is) still unknown."¹⁴⁰

Likewise, Danny Matthews,¹⁴¹ in his witness statement remarked that:-

"there was no structural process of risk assessment in place with respect to BSE before this, or indeed until 1996, although ... this did not preclude *ad hoc* assessments from being made."¹⁴²

And, Thomas Murray¹⁴³ claimed that:-

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"I cannot point to any specific documents where (to my knowledge) risk assessment was discussed in the context of BSE. At the time that I was

¹³⁷ BSE Inquiry (2000) Volume 15, Chapter 5, at paragraph 5.19i.

¹³⁸ Director of the Neuropathogenesis Unit, Edinburgh, 1981-1987.

¹³⁹ Witness statement 97B, at paragraph 11.

¹⁴⁰ Witness Statement 443, at paragraph 9. Statement on behalf of the Masters of Bassett Hounds Association.

¹⁴¹ MAFF Senior Veterinary Officer, Tolworth, 1988-1996.

¹⁴² Witness Statement 94A, at paragraph 27, emphasis added.

¹⁴³ Department of Health Head of Section, Environmental Health and Food Safety Division, 1990-

^{1995;} Spongiform Encephalopathy Advisory Committee Secretariat, 1990-193.

dealing with the matter we did not have the sort of data that we knew we needed."¹⁴⁴

It transpires that this view was shared by a number of scientists advising the government. According to Alistair Cruickshank,¹⁴⁵ risk assessment procedures were not employed in determining means of regulating the threat of BSE. He told the Phillips Inquiry that, although the notion of risk assessment has since become well-established is regulatory decision-making, between 1986 and 1989 it was neither properly understood nor used.¹⁴⁶ He noted that instead of making use of any formal assessment:-

"I think we tended to use another couple of legal concepts ... [I]n dealing with any risk, one would apply the concept of reasonableness ... [I]n some cases it was explicitly stated in legislation. In other cases the advice we got from our own lawyers was that anything we did had to be reasonable. That tended to mean it had to be based on *scientific* advice. If we were purporting to ban something, or restrict its use, we had to have pretty good scientific advice to suggest it should be banned or restricted, or whatever".¹⁴⁷

Thus, in the absence of any formal risk assessment process, risk predictions were bolstered by the innate authority of scientific discourse as a means of attaining any legitimacy. Consequently, explicit statements that the risk of human transmission was 'remote' were accepted simply because they had scientific backing. Despite the fact that, at the height of regulatory decision-making in relation to BSE it had been recognised that there were likely to be *un*known unknowns, as well as known unknowns, the risk of transmission to humans through the consumption of infected tissue was still portrayed as a definable and foreseeable risk. The scientific nature of prediction was crucial in the identification of human transmission as a *risk*, as opposed to an *uncertainty*. As illustrated above, the reliance of science-based foresight on evidence of past occurrences resulted in unequivocal assurances that

¹⁴⁴ Witness Statement 120B, paragraph 5.

¹⁴⁵ MAFF Under Secretary, Animal Health Group.

¹⁴⁶ Transcript number 32, at page 61.

¹⁴⁷ Ibid. at page 62.
patterns of BSE would mirror the findings of previously conducted experiments – that is to say, the dependence of scientific risk analysis on evidence of preceding events effectively marginalised uncertainty in respect of the future. Although MAFF scientists acknowledged, notably on a number of occasions, that where protection of public health was concerned, the range of uncertainty in relation to BSE was great,¹⁴⁸ they continued to utilise knowledge of the past as a means of securing a degree of certainty in respect of the future in their calculations that there was a remote likelihood that BSE would transmit to humans. In doing so, the future hazards were expressed in fixed, rather than uncertain, terms.

This tendency to define the future using the rhetoric of *risk* is not only the product of the backward-looking basis of scientific prediction, but it is also a result of the political dimensions of decision-making. Admittedly, it is difficult to draw any logical distinction between the scientific and political elements of risk decisionmaking, particularly given that both the definition of risk and the process of risk assessment are governed by their social, and thus political, context. However, for the purpose of this section, the construction of risk in the BSE episode is presented as having distinct scientific and political aspects. The following part focuses on the political administration of BSE. It begins with an account of the reassurance offered by government officials that BSE posed no, or little, risk to human health. It goes on to illustrate that, although those reassurances of safety were both naïve and unfounded, they were accurate in that they echoed the reality that there was no evidence that BSE was a risk to humans. Under the heading 'Asking the Wrong Questions', it shows that politicians and MAFF officials were mistaken in their excessive attention to past events. Accordingly, whilst they correctly asserted that there was no evidence that BSE could be transmitted to humans, they were erroneous in their inference that the absence of evidence of risk in the past meant that there was no possible risk in the future. In particular, it draws attention to the unwavering reliance of government officials and policy-makers on scientific evidence, illustrating that decision-making centred on the notion that "the scientific advice must be that there is evidence that such and such occurs before the Government can act to stop

¹⁴⁸ See, for example, witness Statement 103C, at paragraph 12.

it".¹⁴⁹ The following section shows that the marginalisation of uncertainty in the official administration of the BSE crisis was born of a combination of over-reliance of scientific opinion and evidence-based knowledge. As a MAFF official noted, the importance of taking outside views into account in policy-making had not been fully understood.150

¹⁴⁹ Transcript number 32, at page 70, emphasis added.
¹⁵⁰ Witness statement 307, at paragraph19.

<u>Chapter Eleven</u> <u>The bureaucracy of risk: evidence of reason, rationality and</u> <u>positivist hubris</u>

<u>11.0</u> Introduction

The significance of the BSE crisis lies not only in its warnings of the limits of scientific knowledge, but also of the centrality of science in the Government's response to dealing with the unknown. As the Dainton Report of 1971 emphasised:-

"For many years past it has been evident that Government departments need scientific knowledge ... and in some cases large scientific establishments to enable them to carry out their functions ... It is essential that the advice and information from this source be free from considerations of administrative and political convenience; but it does not mean that policies for strategic and basic science should be devised without proper regard for public policy."¹

John Gummer, MAFF Minister of State from September 1985 to July 1988, reflected the findings of the Dainton Report, commenting that:-

"[p]olicy must ... be based on reason. We were to do everything that the scientists thought necessary, including the research they advised ... Once expert advice was obtained, we had to be wary of taking decisions that were not supported by the scientists as that would undermine the credibility of our actions and make the whole policy subjective".²

It is unsurprising that, in the light of the political dependence on scientific knowledge, decision-making in relation to BSE was rooted in a culture of expertise. As a notable

¹ The Future of the Research Council System, Report of a Council for Scientific Policy (CSP) Working Group under the chairmanship of Sir Frederick Dainton, published as an appendix to Government Green Paper (November 1971) Cm 4814, A Framework for Government Research and Development (HMSO; London; 1971) page 12, at paragraph 35.

² Witness statement 311, at paragraph 13.

consequence of the explicit reliance on specialist analysis, definitions of 'risk' were narrowly constructed and founded solely on scientific evidence. Departing from the BSE episode for a brief moment, the following extract illustrates the blinkered nature of scientific definitions of risk. In July 2001, during a public meeting, the Chair of the UK scientific Advisory Committee on Releases to the Environment of GMOs (ACRE), and Robin Grove-White, a member of the Agriculture and Environment Biotechnology Commission (AEBC) advisory body, entered into a discussion of potential environmental impact of GM crops. The discussion not only reveals that scientific interpretations of risk are only capable of accommodating observations of past events, but also that the scientific discourse is incapable of recognising that the future is essentially unknown:-

[AEBC]:	"Do you think people are reasonable to
	have concerns about possible 'unknown
	unknowns' where GM plants are
	concerned?
[ACRE]:	Which unknowns?
[AEBC]:	That's precisely the point. They aren't
	possible to specify in advance. Possibly
	they could be surprises arising from
	unforeseen synergistic effects, or from
	unanticipated social interventions. All
	people have to go on is analogous
	experience with other technologies
[ACRE]:	I'm afraid it's impossible for me to respond
	unless you can give me a clear indication of
-	the unknowns you are speaking about.
[AEBC]:	In that case don't you think you should add
	health warnings to the advice you're giving
	to ministers, indicating that there may be
	'unknown unknowns' which you can't
	address?

[ACRE]: No, as scientists, we have to be specific. We can't proceed on the basis of imaginings from some fevered brow..."³

It is clear that scientific discourse is, conceptually at least, incompatible with the notions of anticipatory action and precaution. Whereas scientific discourse focuses on what is known, the concept of precaution is based on the notion that the future is essentially unknown. In relation to the BSE episode, the affiliation between scientific interpretations of the future and evidential certainty created a situation in which reassurances of the safety of beef were necessarily reliant on the fact that there was no prior evidence of human transmission. The following section focuses on the framing of the threat of human health implications, highlighting that the manner in which the 'BSE problem' was presented was fundamental to the way in which legitimacy was ascribed to reassurances of safety.

<u>11.1 Asking the wrong questions</u>

It is unsurprising that scientific analyses of the potential risk posed by BSE were framed by political demands of certainty. Perhaps one of the most prominent forces in the quest for scientifically-certain knowledge was the prospect of the judicial review of decision-making. So as to avoid the criticism that a particular decision was unfounded, the Government was keen to ensure that its actions could be corroborated by scientific evidence. John MacGregor, Minister for Agriculture, Fisheries and Food between 1987 and 1989, observed that:-

"[the BSE crisis] could have great significance for the industry and therefore I had to be sure of my ground ... We had to have a view of those who could give us the best advice in relation to human health. If we had not taken that, then I think we would have been at risk of challenge, not

³ Taken from a paper delivered at 'Sensing the Unsensed' Workshop at Lancaster University, October 2004: Wynne, B. 'Reflexing Complexity: Post-Genomics Knowledge and Reductionist Returns in Public Science' in which the dialogue is attributed to Grove-White, R. 'personal communication as the AEBC member involved' (Institute for Environment, Philosophy and Public Policy; Lancaster University; 2001).

just judicial review. I could have been challenged in the House of Commons or by the industry."⁴

This pressure to achieve scientific certainty resulted in a rigid and specific framing of the 'BSE problem'. Driven by a need to acquire scientific proof upon which to base its policy and legislation, Government Ministers and officials posed very direct questions about the nature of BSE. Instead of referring to the inadequacy of scientific knowledge or the unknown likelihood that BSE might present a future threat to human health, the Government position was continually framed in terms of the evidence available in relation to human transmission. For example, on 15 October 1987, John Suich of the MAFF Animal Health Division conducted a BSE 'Question and Answer' briefing for the media. He was asked:- "Can it be transmitted to Rather than replying that the threat of human transmission was humans?". scientifically uncertain, he answered:- "There is no evidence that it is transmissible to humans."⁵ Strictly speaking, Suich was correct – there was no evidence to suggest that BSE could jump the species barrier and affect human health. Yet, despite the technical validity of such statements, they provided a tenuous basis upon which to construct assurances of the safety of BSE-infected meat. Nonetheless, declarations that there was no proof that BSE would transmit to humans continued to be seen as affirmation that human transmission was, under any circumstances, impossible. Prime Minister Major insisted that, given that there was "no scientific evidence that BSE can be transmitted to humans or that eating beef caused CJD"⁶ beef was a "safe and wholesome product."⁷ Furthermore, the Chief Veterinary Officer.⁸ in a note addressed to the Parliamentary Secretary, maintained that the lacking evidence of any human health implications demonstrated that cattle was a dead-end host to the disease.9

⁴ The Inquiry into BSE and Variant CJD in the United Kingdom (HMSO; London; 2000) Volume 15, at paragraph 4.65.

⁵ BSE Inquiry (2000) Volume 3, at paragraph 5.27; YB87/10.15/1.3.

⁶ As cited in Dealler, S. F. Lethal Legacy (Bloomsbury Publishing; London; 1996) at page 242.

⁷ Ibid.

⁸ William Rees, August 1980-May 1988.

⁹ YB87/6.5/1.1.

11.2 Absolute uncertainty

On 25 October 1995, the Chief Medical Officer at the Scottish Office remarked that, in relation to BSE "[t]he issue remains, however, that the uncertainty has increased, rather than decreased."¹⁰ In written statement, Sir Richard Southwood,¹¹ Sir Anthony Epstein,¹² William Martin,¹³ and Lord Walton of Detchant¹⁴ observed that when the Southwood Working Party published its report, "no one could quantify the risk at that Although the Government did not explicitly acknowledge the danger of time"¹⁵ transmissibility until March 1996, the potential threat of BSE to human health was acknowledged as being a principal concern from the very outset, almost a decade earlier. On 19 December 1986, approximately a month after BSE was first identified by the Central Veterinary Laboratory, Ray Bradley, Head of the Pathology Department, sent a minute to his colleagues warning that if it transpired that the disease was a strain similar to scrapie, there would be "severe repercussions to the export trade and possibly also for humans if, for example, it was discovered that humans with spongiform encephalopathies had close association with the cattle."¹⁶ During the course of giving oral evidence, he subsequently observed that, despite there being uncertainty as to whether the disease was a human pathogen, it was reasonable, at that time, to suggest that it posed a *possible* risk if infected bovine entered the human food chain.¹⁷ Although there was no evidence to suggest that other animal spongiform encephalopathies could be transmitted to humans, the Chief Veterinary Officer considered that the possibility that BSE was capable of crossing the species barrier should not be ruled out.¹⁸ Similarly, in his written evidence, Alistair Cruickshank of the Animal Health Group, MAFF, described the similarity between bovine encephalopathy and kuru, a human prion disease, as 'worrying'.¹⁹ Of equal significance, when asked if BSE presented any real threat of transmissibility,

¹⁰ YB95/10.25/16.1-16.2.

¹¹ Chairman, Working Party on BSE, 1988-89.

¹² Member of the Southwood Working Party.

¹³ Ibid. ¹⁴ Ibid.

¹⁵ Witness statement 483, at paragraph C5.

¹⁶ BSE Inquiry (2000) Volume 3, at paragraph 5.4; see YB86/12.19/1.1, emphasis added.

¹⁷ Transcript number 29, at page 93.

¹⁸ Transcript number 98, at page 66.

¹⁹ Witness statement 75, at paragraph 2.2.

the Director of the Central Veterinary Laboratory²⁰ admitted that he was unable to provide a categorical answer.²¹

On an examination of the BSE Inquiry and the archived evidence, it becomes apparent that these expressions of incertitude and fear for potential human consequences were endemic in communications between Members of Parliament, government scientists, and policy-makers throughout the episode. It is remarkable, then, that despite the acknowledged uncertainty of the likelihood and implications of the transmission of BSE to humans, the threat of transmission was repeatedly presented as a definable and low risk. Taking as a case study the ten year-period leading up to the official recognition in 1996 of the possible link between CJD and BSE, it is interesting to juxtapose the congenital uncertainty of the threat of transmission with the modelling of risk based on retrospective studies of scrapie.

Concerns that reassurances of safety might not have an accurate basis in scientific evidence were clearly echoed in a letter written by Lord Montagu of Beaulieu to the Minister of Agriculture, Fisheries and Food:-²²

"My concern in writing to you, and indeed the concern of my tenant, is that in present legislation there is nothing which prevents veterinary officers from certifying the carcass of an animal infected with this disease as fit for human consumption. Indeed, it is my understanding that many such cattle many already be sold through abattoirs for this purpose.

At the present time I understand little or no research has been done on whether this disease can be transmitted to humans through consumption of beef from infected animals, and, until this is known, it seems quite wrong to me that it is possible to sell infected carcasses for this purpose. As you will appreciate, there is a substantial financial incentive on farmers to sell a carcass for human consumption, as I understand it is worth approximately £300, as against a price of £50 if sold for pet food. Perhaps

²⁰ William Watson.

 ²¹ BSE Inquiry (2000) Volume 3, at paragraph 5.20.
 ²² June 1987 – July 1989.

this is an area where the Ministry should make the disease notifiable and pay compensation at the full value for animals infected?

I wonder if this is something which should be taken up urgently through your Ministry, at least until a clearance is placed on any possibility of risk arising from the consumption of carcasses affected with this disease."²³

The following year, Alistair Cruickshank, in a minute sent to the Deputy Secretary for Land and Resources²⁴ and copied to officials in MAFF and the Scottish, Welsh and Northern Ireland Offices provided one of the most compelling accounts of the uncertainty of transmissibility:-

"We do not know where this disease came from, we do not know how it is spread and we do not know whether it can be passed to humans. The last point seems to me to be the most worrying aspect of the problem. There is no evidence that people can be infected but we cannot say that there is no risk ... If we believe the risk to human health was so remote as to be negligible we might advise Ministers to ride out the criticism. I would however be reluctant to say the risk is negligible. One theory is that BSE may have originated from sheep affected with scrapie ...If this theory is correct – and I emphasise that this is only one of a number of possible explanations – we have to face up to the possibility that the disease could cross another species gap".²⁵

In a minute to the Minister of Agriculture, Fisheries and Food, the Permanent Secretary at MAFF²⁶ advised that:-

"[i]f you took no action now and worrying positive results were to emerge from these studies, you would have laid yourself open to criticism for not acting to reduce the risks to public health. I do not see how you could

²³ YB87/12.4/1.1-1.2; emphasis added.

²⁴ Edward Smith.

²⁵ YB88/2.16/1.1 at paragraphs 2-3.

²⁶ Derek Andrews, October 1987-February 1993.

defend taking no action now unless you had the support of the Chief Medical Officer."²⁷

In his written statement to the Inquiry, the Permanent Secretary recalled that:-

"my overriding concern at the time [February 1988] was the possible risk to human health. I felt that the correct way forward on the basis of the information we had was to introduce a slaughter and compensation policy as soon as possible."²⁸

Expressions of concern that BSE might be more dangerous than scientific studies suggested have been documented throughout the episode. During an interdepartmental meeting attended by Sir Donald Acheson,²⁹ Department of Health Officials, Alistair Cruickshank,³⁰ William Watson,³¹ Joan Davies,³² and Dr Galbraith,³³ it was accepted that there was probably no risk in drinking milk or eating meat of infected cattle, although the position was far less clear about consumption of brains, spleen and other organs.³⁴ The Chief Medical Officer concluded that, although he suspected that there was no risk posed to humans, it could take 30-40 years to establish this with any degree of certainty.³⁵ In an article published in *Farming News*, Tony Andrews of the Royal Veterinary College, when asked whether BSE could affect humans, answered "we simply don't know".³⁶ Furthermore, Alistair Cruickshank noted that "[t]he problem is that we cannot say there is no risk – indeed, I do not think we can even say the risk is insignificant."³⁷ Yet, the official position continued to reflect the argument that there was no risk to human health.

²⁷ YB88/2.24/2.1.

²⁸ Witness statement 281, at paragraph 35.

²⁹ Chief Medical Officer, Department of Health.

³⁰ Under Secretary, Animal Health Group, MAFF.

³¹ Director of the Central Veterinary Laboratory.

³² Public Health Laboratory Service.

³³ Communicable Disease Surveillance Centre.

³⁴ YB88/3.17/7.1.

³⁵ *Ibid*.

³⁶ YB88/4.22/6.1.

³⁷ YB88/2.26/4.1.

<u>11.3 Reassurances of safety</u>

In the ten years prior to 1996, dialogue between scientists, government officials, and politicians assured, with exuberant confidence, the safety of British beef. This was true not only of government-authorised communications of the risk of human infection, but also of confidential exchanges that the Phillips Inquiry has since disclosed. Indeed, the Inquiry concluded that repeated assertions of the safety of beef conveyed the message not only that consumption posed no human threat, but also that the BSE agent was, in epidemiological terms, incapable of jumping the species barrier.³⁸ This 'risk-free' rhetoric came to dominate expert findings at a remarkably early stage of the episode, and, notwithstanding deficient knowledge, disputed values, high stakes, and urgency of action, definite statements of 'low-risk' or 'no risk' continued to dictate decision-making until it became clear that predictions made on the basis of 'sound science' were entirely unsound. Whilst these risk-based judgments drew legitimacy from the innate authority of scientific discourse and the 'privilege of experience',³⁹ it transpired that findings of the 'establishment' expertise were intrinsically flawed in two different senses. Not only were forecasts about the transmissibility of BSE incorrect, but the mechanism, deriving from orthodox scientific assessment, and used to project observations of the scrapie-protein into the future as a means of predicting the epistemological behaviour of BSE, failed to appreciate the capricious autonomy with which the future materialises.

In order to fully illustrate the discrepancy between, on the one hand, reassurances of safety, and on the other, the inability of scientific risk assessment to predict the nature, occurrence, and magnitude of potential hazards, this section begins with an analysis of the communication of the implications of BSE to human health. It draws on a sample of exchanges between those within the organisational structure of Government. Although initial communication about BSE within MAFF went largely undocumented,⁴⁰ it is still possible to identify the prevailing belief that, since scientific studies failed to turn out evidence of *previous* human transmissibility, the logic of deduction prescribed that there was no risk of transmissibility in the *future*. It

³⁸ BSE Inquiry (2000) Volume 1, page xxi, at paragraph 5.

³⁹ Williams, G. and Popay, J. 'Lay Knowledge and the Privilege of Experience', in Gabe, J. et al (eds) Challenging Medicine (Routledge; London; 1994) pages 118-139.

⁴⁰ BSE Inquiry (2000) Volume 3, at paragraph 1.37.

is therefore especially interesting to note that, despite having been presented as a matter of scientific certainty, repeated reassurances of safety were, in fact, based merely on provisional opinion. Whereas the credibility of claims of 'no-risk' is traditionally seen as being contingent on its scientifically-verified underpinning, it transpires that assurances of safety had no basis in conventional risk assessment.

This section adopts a distinct perspective on the marginalisation of uncertainty, capturing the incongruity between scientific assessment, with its ostensible mastery of risk and disciplinary purity, and the capacity of scientific risk discourse to conceal not only the socially-negotiated process of definition, but also its inability to engage with the future in any meaningful sense. Naturally, this raises serious questions about the utility of scientific risk assessment as a tool for decision-making in relation to prospective contingencies. But, before turning to examine the broader themes emerging from the BSE episode, it is necessary to briefly recall some explicit statements of the safety of the human consumption of beef in order to add substance to the argument that reassurances were a key feature in the administration of the disease.

Early in 1987, the Head of the CVL Pathology Department, commenting on the nature of BSE, insisted that it was essential that MAFF kept "an open mind"⁴¹ regarding the potential human health implications of BSE. Unfortunately, this pursuit for open mindedness was lost to scientific and political demands of certitude in prediction, resulting in premature and idealistic testimonies of safety. Four months on, in a note addressed to the Parliamentary Secretary, the Chief Veterinary Officer made a pivotal statement on the subject of transmissibility. He claimed that there was no evidence that the bovine disorder was transmissible to humans, and, in the absence of such evidence, it was inappropriate to impose any restrictions on affected farms or the sale of produce from affected cattle herds.⁴² Accordingly, any 'irresponsible or 'ill-informed' publicity would induce "hysterical demands for immediate, draconian government measures",⁴³ and that, given the lack of epidemiological records pointing to its origin, infectivity, potential transmission routes, and animal susceptibility, the

⁴² YB87/6.5/1.1.

⁴¹ YB87/2.4/2.1.

⁴³ Ibid.

possibility of human health implications was so remote that the implementation of anticipatory measures was indefensible, both in terms of cost-effectiveness and feasibility.

The essence of this statement came to be a central theme of the official response to BSE, dominating the approach taken in dealing with the threat of cross-species transmission. In December 1987, in an article published in Farmers Weekly, the CVL declared that, given that there was no evidence that cattle, nor any other species, had become diseased as a result of contact with other species, BSE did *not* present any danger to humans.⁴⁴ Yet, curiously, notwithstanding the fact that it was alleged that humans were insusceptible to the disease, MAFF subsequently established a scientific advisory committee, under the chairmanship of Sir Richard Southwood ('the Southwood Working Party'), to examine any potential human and animal health implications of BSE.

A month later, and contrary to suggestions of its safety, Holt and Phillips published an article in the *British Medical Journal* claiming that the BSE agent posed a very real threat to public health.⁴⁵ They argued that there was no way of telling which cattle were infected until symptoms developed, and, if transmission to man had already occurred it might be some years before affected individuals displayed signs of infection.⁴⁶ Furthermore, they suggested that it was possible, although at that stage unproven, that asymptomatic cattle could be as infective as symptomatic animals.⁴⁷ Similar concerns about the latent effects of BSE were raised by a number of other scientists and physicians outside government.⁴⁸ Presenting evidence to the Agriculture Select Committee, a Professor Emeritus of Clinical Microbiology submitted that "we do not know if [beef] is safe",⁴⁹ adding that it "could well contain

⁴⁴ YB87/12.11/2.1.

⁴⁵ Holt, T. A. and Phillips, P. J. 'Bovine Spongiform Encephalopathy' (1988) 296(6636) British Medical Journal 1581-1582.

⁴⁶ *Ibid*.at page 1582.

⁴⁷ Ibid.

⁴⁸ See, for example, evidence given by Professor Richard Lacey and Dr Helen Grant, House of Commons Agriculture Select Committee Fifth Report, *Bovine Spongiform Encephalopathy* (HMSO; London; 1989) Minutes of Evidence at pages 43-45.

⁴⁹ *Ibid.* at page 43.

three components that could make it dangerous"⁵⁰ - nerves; lymphatics and lymph nodes; and, infected material from the opening up of the brain and spinal cord.

In an attempt to allay these fears, the Southwood Working Party reported that the threat of transmission to humans was 'remote',⁵¹ and that it was 'most unlikely' that BSE would have any implications for human health.⁵² On the back of these findings, Ministers and officials made explicit statements that there was "no risk, or indeed any proof or such a risk"⁵³ to public health.

It is important to draw a clear distinction between the actual findings of the Southwood Report, and the way in which they were subsequently interpreted. Whilst it is true that it concluded that it was 'most unlikely' that BSE would have any implications for human health, it also warned that the validity of those findings was limited to the extent that knowledge about the disease was incomplete. Regardless of its position that the risk posed by BSE was minimal, the Report considered that it would be 'extremely serious' if the assessment of the likelihood of human transmission was incorrect,⁵⁴ noting that its long incubation period might lead to it being "a decade or more before complete reassurance can be given".⁵⁵ Yet, notwithstanding these caveats, the Southwood Report was repeatedly upheld as illustrating that, by way of robust scientific inquiry, the risk of human transmission was either nonexistent, or negligible.

In written statement, the Working Party claimed that their findings were founded on a conventional analysis of risk, defining 'risk' as a combination of both the likelihood, and the scale of danger, of an impending hazard.⁵⁶ However, a careful reading of the Southwood Report reveals that, contrary to its claim that it based its findings on scientific risk assessment, the conclusion that the risk of transmissibility was 'remote'

⁵⁰ Ibid.

 ⁵¹ The Department of Health, and the Ministry of Agriculture, Fisheries and Food, *Report of the Working Party on Bovine Spongiform Encephalopathy* (HMSO; London; 1989) at paragraph 5.3.5.
 ⁵² YB89/2.17/1.3.

⁵³ Keith Meldrum, Chief Veterinary Officer at MAFF, statement to the EU's Standing Veterinary Committee, cited in European Parliament, *Report on Alleged Contraventions or Maladministration in* the Implementation of Community Law in Relation to BSE, Without Prejudice to the Jurisdiction of the Community and National Courts, A4-0020-/97 (European Parliament; February 1997) at page 9.

⁵⁴ BSE Inquiry (2000) Volume 4, at paragraph 10.40

⁵⁵ DoH and MAFF (1989) at paragraph 5.3.1.

⁵⁶ Witness statement 483, at paragraph 6.

was, at most, a product of inference rather than scientifically-verified foresight. Not only did the Report fail to make clear the grounds upon which the professed risk assessment had been made,⁵⁷ but it also used the terms 'most unlikely' and 'remote' to describe the risk to human health without any explanation of their meaning.⁵⁸ Thus, whilst the Report is portrayed as imparting a scientifically-assessed calculation of risk, its predictions were essentially a matter of "judgement in the face of uncertainties",⁵⁹ devoid of any footing in risk assessment. Acknowledging the absence of any *explicit* analysis of the risk posed, the Phillips Inquiry found that the conclusion that humans were unlikely to be susceptible to the BSE agent "was not founded on a scientific understanding of the factors governing the transmission of TSEs in general",⁶⁰ and described it simply as a product of uneducated guesswork.⁶¹

At this stage, two issues come to mind. First, the findings of the Southwood Report were selectively interpreted; and second, its outwardly-scientific nature was perceived as a means of ensuring authoritative definitions of risk. What is intriguing about the way in which the Southwood Report was understood by Ministers and government officials was that, despite the fact that it lacked any formal risk assessment to substantiate its claims, it was consistently construed as credible evidence of a '*very* remote risk'.⁶² To argue, as many did, that the Report was a clear indication that it was highly improbably that the threat of cross species transmission would materialise is a misguided exaggeration of the esteemed position occupied by science. Such an outlook laid undue emphasis on unambiguous statements deriving from scientific evidence, whilst at the same time disproportionately overlooking more tenuous statements based on opinion, rather than fact.

This tendency to regard the Report's findings as having an infallible quality was captured in a statement made by Prime Minister Thatcher in February 1989. Responding to a question posed by an MP sitting on the Opposition benches regarding the validity of the Southwood Report, Thatcher was adamant that its findings were

⁵⁷ BSE Inquiry (2000) Volume 4, at paragraph 10.36.

⁵⁸ *Ibid.* at paragraph10.21.

⁵⁹ *Ibid.* at paragraph10.31.

⁶⁰ Ibid.

⁶¹ Ibid.

⁶² MAFF News Release 27 February 1989, IBD1, table 3, at page 3, emphasis added.

valid, irrespective of the fact that they were both uncorroborated and tentative. She argued that:-

"[w]e set up a committee of experts under Professor Southwood. We published the report in full. We referred it to the Chief Medical Officer of Health and we accepted the recommendation of both, precisely. There is no point whatsoever in setting up a committee of experts, in having a Chief Medical Officer of Health, in receiving their advice and then not accepting it. We would rather accept their advice than that of the hon. Gentleman."

Echoing Thatcher's sentiments, scientific expertise continued to provide a pivotal force in the administration of the BSE crisis. Further, in-keeping with the rationalist tradition, decision-making maintained the distinction between scientific and non-scientific knowledge. As a result of the import attributed to scientific analysis throughout the BSE, decisions founded on scientific knowledge were perceived as being more credible than those without a scientific basis.

It is particularly interesting to note that a position of 'minimal risk' to humans was adopted, despite that fact that studies conducted subsequent to the Southwood Report confirmed that the BSE agent had been successfully transmitted to a number of different species during controlled scientific experiments. This finding undoubtedly conflicted with the Report's conclusion that cattle was a dead-end host to the disease. Crucially, the range of species becoming infected with BSE was notably wider than that observed with scrapie,⁶³ leading the BSE Inquiry to conclude that these findings were entirely "consistent with the possibility that BSE was transmissible to humans."⁶⁴ However, at the time, Government officials were adamant that the laboratory conditions in which cross-species transmission had occurred were not reflective of nature, and that there was no scientific evidence to suggest that the human consumption of beef posed any health risk. In a press release, MAFF claimed that, given that similar results had been previously obtained in experimental studies of the transmission of scrapie to mice, the oral transmission of BSE to another species

⁶³ BSE Inquiry (2000) Volume 6, at paragraph644.

⁶⁴ Ibid.

merely confirmed that transmission to humans was improbable – stating that the results provided "further evidence that BSE behaves like scrapie, a disease which has been in the sheep population for over two centuries without any evidence whatsoever of being a risk to humans."⁶⁵ Reinforcing the claim that British beef posed little danger to consumers, the Chairman of the Meat and Livestock Commission, after having consulted MAFF, stated that:-

"[t]op British and European vets and scientists advising the European Community have studied the disease very carefully. They are agreed that everything necessary to protect public health is being done and they do not consider there is any danger to public health."⁶⁶

The question of safety came into sharp focus through the media, which, unsurprisingly, became a key conduit through which such reassurances could be challenged. In the months following the revelation of cross-species transmission, television, radio, and newspaper reports were saturated with stories of the '*Mad Cow Threat to Humans*',⁶⁷ and claims that '*Mad Cow Meat May Still Reach Dinner Table*'.⁶⁸ An article in *The Independent* quoted scientists at the Neuropathogenesis Unit as accepting that there was a 'remote possibility' that the BSE agent was capable of passing from infected cows to humans.⁶⁹ A press report published in *The Sun* warned that BSE could present the biggest threat to human health since the bubonic plague.⁷⁰ In two separate interviews, Professor Richard Lacey⁷¹ claimed that "in the years to come our hospitals will be filled with thousands of people going slowly and painfully mad before dying,"⁷² and described BSE as "the greatest of all the foodborne dangers and may kill five per cent of the population within a generation."⁷³ In

⁶⁵ YB90/2.01/10.1.

⁶⁶ YB90/1.22/4.3-4.4.

⁶⁷ YB90/2.02/5.1.

⁶⁸ Ibid.

⁶⁹ North, R. 'Cattle with Cow Disease "On Sale for Slaughter" (4 January 1990) *The Independent*, as cited in BSE Inquiry (2000) Volume 1, Chapter 6, at paragraph 645.

⁷⁰ Coleman, V. '10 Reasons Why We Should Treat Mad Cow Like Black Death' (12 May 1990) The Sun, as cited in BSE Inquiry (2000) Volume 1, at paragraph 653.

⁷¹ Emeritus Professor of Clinical Microbiology.

⁷² YB90/3.01/14.1.

⁷³ YB89/10.00/1.1-1.4.

that "some genetically susceptible people may have become infected with material by eating meat products."⁷⁴

The fraught relationship between the media, on the one hand, issuing alarming claims that the Government had taken too lightly the threat of human transmission, and red tape announcements, on the other, that British beef was safe to eat, was a recurring theme throughout the episode. Understandably, MAFF and other advisory bodies were concerned that the disclosure of information likely to deter the public from eating beef be avoided. There has already been widespread recognition that the ability of MAFF to properly regulate the potential threat of BSE was hindered by divided loyalty between the protection of public health and the safeguarding of the agricultural economy. A number of academic commentators have observed that, on balance, the protection of commercial interests surpassed the protection of human health.⁷⁵ It is therefore unnecessary to pursue this point in much detail. At this stage, it is suffice to note that there existed a tension between MAFF's two principal focuses.

In-keeping with the Government's long-standing position, the Technical Director of the Meat and Livestock Commission declared that "[a]ll the scientific evidence – as opposed to rumour, conjecture and guess – provided by the leading veterinary surgeons and scientists in the UK and the rest of the EEC has indicated that UK beef is perfectly safe to eat."⁷⁶ In the same month, and after having described the risk of human transmission as 'remote and theoretical', the MAFF Food Safety Directorate issued a public statement maintaining that British beef was "not a public health risk and can be eaten with complete confidence."⁷⁷ Reaffirming this position, the Chief Medical Officer, Sir Donald Acheson, in a television interview, stated that "there is no risk associated with eating British beef". Laying emphasis on the implausibility of transmission, and the undisputed validity of scientific advice, he claimed that:-

⁷⁴ YB90/2.02/5.1.

⁷⁵ See, for example, Little, G. 'BSE and the Regulation of Risk' (2001) 64 MLR 730-756, at pages 742-

^{744.}

⁷⁶ YB90/5.14/3.1.

⁷⁷ YB90/5.15/15.1.

"I have taken advice from the leading scientific and medical experts in this field. I have checked with them again today. They have consistently advised me in the past that there is no scientific justification for not eating British beef and this continues to be their advice. I therefore have no hesitation in saying that beef can be eaten safely by everyone, both adults and children, including patients in hospital."⁷⁸

In order to bolster claims of safety, and following the recommendation of the Southwood Report that an expert committee be established,⁷⁹ the Government announced the setting up of the Consultative Committee on Research into Spongiform Encephalopathies to advise MAFF on work already proposed or in progress on transmissible spongiform encephalopathies and priorities for future research. The Committee was chaired by David Tyrrell, a microbiologist who was Director of the Medical Research Council Common Cold Unit, and it subsequently came to be referred to as the 'Tyrrell Committee'. Other Committee members included William Watson, Director of the CVL; Professor John Bourne, Director of the Institute for Animal Health; Robert Will, Consultant Neurologist at the Western General Hospital in Edinburgh; and Richard Kimberlin, ex-Acting Director of the Neuropathogenesis Unit, who had retired and founded an independent consultancy advising on TSEs.⁸⁰

From the outset, the Tyrrell Committee recognised the potential implications of BSE, observing that there would be very serious consequences should the findings of the Southwood Working Party turn out to be incorrect. In stressing the importance of more rigorous investigations into the epidemiology of the BSE agent, the Committee noted that:-

"[t]his concern about BSE not being a dead-end infection, that it might possibly become a naturally endemic infection in cattle, not only had tremendous implications to animal health, the future of the epidemic, but it had implications to public health, because if the disease was not going to go away, then it would obviously present much more of a public health

⁷⁸ YB93/3.11/1.1.

⁷⁹ DoH and MAFF (1989) at paragraph 8.5.

⁸⁰ BSE Inquiry (2000) Volume 1, at paragraph 286.

problem than if it were to go away in due course. So the two things are extremely important, and I think were of major significance to us in focusing on quite a lot of the research programme, to anticipate that.⁸¹

In particular, David Tyrrell expressed concerns about the way in which Southwood Report had dealt with the human health issue, noting that in hindsight, he would have:-

"given more emphasis to the probable large numbers of [subclinically] infected cattle which would be by now around, and what we were going to do about them, and something ought to be done, because that is where risks for the human population would mainly arise."⁸²

In response to the Committee's recommendations that a thorough examination of the disease be undertaken, the Government established a new expert standing committee – the Spongiform Encephalopathy Advisory Committee (SEAC) – to review BSE research and to provide policy advice "on almost every decision that the Government was faced with in handling BSE."⁸³ SEAC was chaired by David Tyrrell, and, although its membership changed and enlarged over time, its inaugural members were Robert Will, William Watson, and Richard Kimberlin of the former Tyrrell Committee, and virologist, former Deputy Director of the Animal Virus Research Institute, and former member of the Agricultural Research Council Committee on Scrapie, Professor Fred Brown.⁸⁴

In a letter to the Chief Medical Officer,⁸⁵ SEAC was unyielding in its conclusion that the threat posed by BSE to human health was insignificant. It stated that:-

"[i]n our judgement any risk as a result of eating beef or beef products is *minute*. Thus we believe that there is *no scientific justification for not eating British beef* and that it can be eaten by everyone."⁸⁶

⁸¹ Transcript number 6, at page 42; see also BSE Inquiry (2000) Volume 11, at paragraph 2.36.

⁸² Transcript number 6, at page 36.

⁸³ BSE Inquiry (2000) Volume 1, at paragraph 294.

⁸⁴ *Ibid.* Volume 11, at paragraph 4.18.

⁸⁵ YB90/7.24/3.1-3.12.

The Committee went on to note that "any theoretical 'BSE risk' in British beef is *so remote that for practical purposes it can be ignored.*"⁸⁷ SEAC's unequivocal stances that British beef could be eaten safely by everyone remained the cornerstone of the Government's policy throughout the episode.⁸⁸ Even after the death of two dairy farmers in 1993, Robert Will,⁸⁹ in an article published in *The Lancet*, claimed that "a causal link with BSE is at most conjectural". In relation to the death of the second farmer, the National CJD Surveillance Unit – established in May 1990 at the Western General Hospital in Edinburgh to assess the epidemiological characteristics of CJD and to determine whether its occurrence was linked to BSE⁹⁰ – concluded that there was no evidence to suggest that it was anything other than a case of sporadic CJD.⁹¹ Subsequent reports that a teenager, Vicky Rimmer, suffered from an unidentified neurodegenerative disease gave rise to widespread speculation that she had been infected as a result of eating BSE-contaminated meat. During a period of intense media coverage, Professor Richard Lacey was cited by the *Daily Mirror* as saying that:-

"I am convinced CJD can be caused by eating meat from cows infected by Mad Cow Disease. The only explanation for this 16-year-old girl's condition is that it came from contaminated beef."⁹²

In a further article, published in The Times, Professor Lacey insisted that:-

"We know the most likely food is processed food, the burgers and sausages. We have to assume it was these products, from cows, that caused the disease and we think this is the first *certain* case of BSE infecting a member of the human race by this method."⁹³

⁸⁶ YB90/7.24/3.2, at paragraph 7.

⁸⁷ YB90/7.24/3.3, at paragraph1.3.

⁸⁸ Witness statement 251, at paragraph90.

⁸⁹ Director of the CJD Surveillance Unit.

⁹⁰ BSE Inquiry (2000) Volume 8, at paragraphs 3.2-3.5.

⁹¹ YB93/7.12/1.1.

⁹² YB94/1.26/20.1.

⁹³ YB94/1.26/16.1, emphasis added.

In response to these claims, which were perceived by the Government as unwarranted attempts at scare-mongering, Sir Kenneth Calman, Chief Medical Officer at the Scottish Office, issued a statement confirming that there was no evidence that BSE caused CJD and, similarly, no evidence that eating beef caused CJD. He noted that:-

"[m]y position as the Government's Chief Medical Officer means that I must provide the best advice to the public, whatever the consequences. If there was any evidence that suggested a link, then I would regard it as my responsibility to bring it to public attention."⁹⁴

This presumption that lacking evidence of human transmission was definitive proof that future human infection was unlikely became central to the political administration of the BSE crisis. Against a background of public anxiety about the safety of bovine meat and products, Ministers and officials became all the more wary of taking decisions that were not supported by scientific evidence for fear that it would undermine the credibility of their actions and expose policy to the criticism of subjectivity. The Minister of Agriculture, Fisheries and Food, for example, testified that "there is no evidence whatsoever that BSE causes CJD and, similarly, not the slightest evidence that eating beef or hamburgers causes CJD."⁹⁵ This outlook was endorsed by the Chief Medical Officer for Scotland, who, on learning that schools and caterers were removing beef from the menu, pointed out that:-

"[t]he Government's independent scientific advisors are saying consistently that there is no evidence at all that eating beef or other foods derived from beef is dangerous. My general advice to people is therefore to carry on eating what you want to eat as you were before. We have no evidence of any connection between BSE and CJD."⁹⁶

On countless occasions, government officials were unwavering in their attempts to restore public confidence in British beef. In a press release issued by the Department of Health in October 1995, Sir Kenneth Calman avowed that there was no evidence of

⁹⁴ YB94/1.26/3.1.

⁹⁵ Cited in Consumers in Europe Group, BSE: Briefing and Recommendations from Consumers in Europe Group (Consumers in Europe Group; London; 1996) at page 1.

⁹⁶ YB95/12.07/12.1.

a link between meat eating and the onset of CJD and that beef was perfectly safe to eat.⁹⁷ Similarly, in February 1996, a Meat and Livestock Commission briefing paper stated, categorically, that British beef posed no risk to human health, and that "[t]he existence of BSE in cattle and the similar disease in humans, CJD (Creutzfeldt Jakob Disease) does not imply any link between the two".⁹⁸

These explicit statements, suggesting in *absolute* terms that beef infected with the BSE agent would not harm consumers, held considerable sway over the political response to the epidemic. An exercise in comparing the political *interpretation* that lacking evidence of human transmission implied that BSE was unlikely to pose any risk to human health in the future, and the *reality* that origin, nature, and behaviour of the BSE agent were scientifically uncertain, is perhaps proof that the disparity derived from semantic inconsistency rather than any deliberate attempt to mislead the public. In giving evidence to the Phillips Inquiry, Sir Donald Acheson testified that "[i]t was several years after the events that I became aware that for some people the word 'safe' without qualification means zero risk."⁹⁹ In fact, it was not until September 1996 – some six months after the Government acknowledged that the most likely cause of CJD was BSE – that the Chief Medical Officer first conceded that such definite and unconditional reassurances of 'no risk' or 'negligible risk' were inappropriately applied, in the circumstances.¹⁰⁰

<u>11.4 Controlling the agenda</u>

It can be said that MAFF's reticent approach – its initial denial followed by a reluctant admission of minimal risk – mirrored its response to previous health scares. The sharp increase in *Listeria*-related disease in the 1970s and 1980s provoked MAFF's Central Public Health Laboratory to prohibit the release of any information

⁹⁹ Witness statement 251, at paragraph92.

⁹⁷ YB95/10.05/7.2.

⁹⁸ YB96/1.3/4.1-4.2.

¹⁰⁰ As cited in Bartlett, D. M. C. 'Mad Cows and Democratic Governance: BSE and the Construction of a "Free Market" in the UK' (1999) 30 Crime Law & Social Change 237-257, at page 244.

about food and food poisoning. At first, MAFF announced that not only did *Listeria* not cause disease, but it was not even associated with food.¹⁰¹

An information embargo during the BSE crisis occurred on two levels. There was a distinct failure, on the part of MAFF, to disclose full and accurate information about BSE, first, to other Government departments, and second, to the public.¹⁰² This section focuses on the restricted communication between MAFF and the Department of Health prior to March 1988. It illustrates that the interplay between the two departments was central to the premise that there was no risk, or that there was a negligible risk, of human transmission. Restrictions imposed by MAFF on communication to the Department of Health were pivotal in shaping the finding that the risk of repercussions to human health was remote.

A MAFF scientist recalled that "in December 1986 when recognition of the disease began to crystallise, we were at the Central Veterinary Laboratory placed under strict confidentiality as to discussing it with outside people".¹⁰³ The Phillips Inquiry also acknowledged that, during the first half of 1987 "there was a policy of restricting, even within the State Veterinary Service, the dissemination of any information about the new disease."¹⁰⁴

The allocation of administrative responsibilities was such that MAFF was accountable for consumer protection as well as matters falling within veterinary expertise, whilst the Department of Health was charged solely with human health surveillance.¹⁰⁵ However, as this section illustrates, this division was not sustained in reality. In fact, by deliberately restricting communication with the Department of Health, MAFF initially retained control over the administration of the potential impact on human health. The resulting imbalance in the distribution of responsibility between MAFF and the Department of Health was pivotal in the construction of risk. It is shown that, although MAFF controlled the development of measures designed to deal with the

¹⁰¹ Dealler, S. F. (1996) see pages 31-3 and 165-6.

¹⁰² BSE Inquiry (2000) Volume 3, at paragraph 2.6.

¹⁰³ Ibid.

¹⁰⁴ *Ibid.* at paragraph 2.137.

¹⁰⁵ BSE Inquiry (2000) Volume 1, at paragraph 1225.

potential impact of BSE on human the health, it lacked expertise, not only in relation to TSEs in general, but also in respect of strains known to infect humans.

Alistair Cruickshank explained that the restricted distribution of information had its roots in the belief within MAFF that it was highly unlikely that BSE was capable of jumping the species barrier, rendering unnecessary any interaction with the Department of Health. The following extract makes it clear that the decision to sidestep consultations with the Department of Health was a consequence of a preceding assumption of the improbability of human transmission. Cruickshank was of the opinion that:-

"the implications of BSE for public health were considered as soon as the similarities with other diseases emerged. For many months the information available was too scanty to permit any conclusions to be drawn. In any case although there did appear to be similarities to certain very rare human diseases, there was also a similarity with the very common sheep disease, scrapie, which had no known implications for human health. The latter point was seen as more significant than the former. Throughout this period my understanding was that DHSS [i.e. the Department of Health] were taking the same view as MAFF, namely that any decisions on action would have to await further information. This seemed entirely reasonable at the time."

In a written statement, the Chief Veterinary Officer confirmed that the decision to curtail the transfer of information to the Department of Health merely reflected the fact that MAFF was already confident that the impact of BSE was confined to cattle. He made his position clear, stating that:-

"[a]lthough the number of cases of BSE increased in the latter half of 1987, there were no developments that caused me to change my opinion that there was no reason to believe that BSE might present a danger to humans...

It is worth noting that if (a) I had reason to believe between December 1986 and March 1988 that BSE might present a danger to humans (even though other spongiform encephalopathies, indeed TSEs, were not recognised as a potential danger); and (b) a minimum amount of scientific information about BSE had been collated, I would formally have informed the DHSS, who would have primary responsibility for producing any reasoned examination of possible implications for humans. However, the factors set out at (a) and (b) above were not in my opinion fulfilled."¹⁰⁶

It is crucial that, in addition to indicating that it had already been established that the risk of human transmission was negligible, the lack of interaction between MAFF and the Department of Health was fundamental in ascribing credence to the claim that it was most unlikely that BSE would affect humans. In other words, the failure to disclose information to the Department of Health was the product, as well as the source, of the construction of risk during the BSE crisis. Not only did it expose that MAFF had interpreted the threat of transmission as 'nonexistent' or 'remote', but it also engendered a perception that the BSE agent was only capable of infecting animals. Thus, not only did the information embargo emulate an accepted construction of risk, it simultaneously gave rise to the impression that the risk was minimal. The fact that MAFF prohibited the release of information was itself a seminal factor in shaping the expression of risk.

In June 1990, Hilary Pickles of the Department of Health remarked that:-

"[t]he most serious delay was in informing DH in the first place. The CVL were aware of a new disease in January 1987, they informed their Ministers in June 1987, but wrote to us . . . only on 3 March 1988, by which time they had 500 cases."¹⁰⁷

¹⁰⁶ Witness Statement 3, at paragraphs 38-9.

¹⁰⁷ YB90/6.1/3.1.

She went on to note that:-

"[a]t a day to day working level there appear no problems, and direct requests for information known to exist have not been refused. The difficulty is with information that is not being volunteered in the way we would expect with full trust and cooperation. If we not know about it, we do not know to ask for it."¹⁰⁸

It is significant that, although it was documented that several MAFF scientists had expressed concern regarding their limited expertise in relation to human TSEs and inability to predict the behaviour of BSE, MAFF continued to control the handling of the potential threat posed by BSE to human health. Despite the fact that, in a meeting on the 22 July 1987, both the MAFF Permanent Secretary Sir Michael Franklin and Parliamentary Secretary Donald Thompson stressed the importance of a specialist investigation into all possible consequences of human infection, responsibility for human health remained with MAFF – primarily because of its failure notify the Department of Health of the its endeavours. In a landmark statement, the Head of the CVL's Pathology Department commented that:-

"[the] CVL did not have any medically trained staff and was not in a position to make a detailed assessment of the possible risk that BSE could transmit to man. Neither was the necessary expertise to make this type of assessment available elsewhere in MAFF. Assessment of the possible risk to man was a matter for the Department of Health, who had the necessary medical expertise to consider these matters. Initially CVL, and MAFF generally, set about gathering together as much information as possible about the new disease in cattle to allow MAFF to assess the risk to animal health and allow others to assess the risk to human health."¹⁰⁹

Hence, given that MAFF was incapable of conducting a thorough assessment of the human health risks stemming from BSE, it can be said that its interpretation of risk more accurately reflected its commitment to protecting the commercial interests of the

¹⁰⁸ YB90/6.01/3.1.

¹⁰⁹ Witness statement 71D, at paragraph 15.

agricultural export industry. From this perspective, it is clear that the definition of risk propounded by MAFF was contextually dependent on scientific prognoses that took into account political and commercial dynamics of the threat of BSE. In the words of Winter:-

"So here we have a situation where the politicians could claim, on scientific grounds, that a ban was not necessary whereas the scientists only came to this conclusion because of their perceptions of the political unacceptability of a ban."¹¹⁰

Whilst it is clear that scientific findings underpinned the political administration of the disease, it must also be borne in mind that the definitions of risk emanating from scientific assessment were shaped by the political and commercial climate. To some extent, the notion of risk running through the BSE episode confirms the inescapability of a subjective construction of the future. And, given that it is a socially constructed concept, there is no obvious reason why risk cannot be defined in a more inclusive manner. The real constraint throughout was an indisputable lack of knowledge. With a disease with such a long incubation period, and without any tests for infection, it was obvious that a better understanding of BSE would not be achieved for some time.¹¹¹ Nevertheless, the practice of disguising political decision-making with seemingly objective and certain scientific evidence continued to govern the handling and control of BSE. This relationship between science and managing the unknown was particularly evident in the legislative response to the disease.

¹¹⁰ Winter, M. 'Intersecting Departmental Responsibilities, Administrative Confusion and the Role of Science in Government: the Case of BSE', [1996] Parliamentary Affairs 550, at page 563.

<u>Chapter Twelve</u> <u>Legislative response to scientific uncertainty</u>

12.0 Introduction

A study of the legislative response to BSE is useful in that it reveals the capacity of law to act in the face of scientific uncertainty. Here it is shown that the credence attributed to scientific analyses that construed the risk of BSE transmission to humans as 'low' or 'negligible' precluded legislation from providing an anticipatory recourse to the disease. Although MAFF officials were adamant that the legislative framework was founded on the precautionary principle, reliance on the notion of precaution was, in fact, merely superficial. An examination of legal measures adopted in the face of BSE illustrates that undue prominence was ascribed to the notion of scientific certainty, rendering ostensible the practical implication of precaution.

This section introduces the major pieces of legislation enacted in response to the human health risk posed by the BSE agent. In doing so, it illustrates that the approach adopted by the Government in managing the threat of BSE was preventive, rather than precautionary. This preventive/precaution distinction is central to the argument that scientific means of risk analysis are incompatible with the application of precautionary measures. It is important to keep in mind that whilst the working definition of the precautionary principle requires that, in the face of scientificallyunknown risks, steps are taken to avoid potential harm, preventive measures are only implemented as a means of dealing with scientifically-known risks. The process of risk assessment, which is traditionally underpinned by the tenets of scientific discourse, reflects the assumption that the ideals of scientific certainty are realised through definite statistical expressions of reality. Conventional practice dictates that articulating the unknown is best achieved by projecting the past into the future. The extent to which the past has been observed and quantified inevitably determines whether the future can be predicted with scientific certitude. Thus, being able to distinguish between scientific uncertainty and scientific certainty is fundamental to the task of determining whether precautionary or preventive action is taken. Because

scientific risk assessment is inherently dependent on *certain* and *absolute* expressions of the future, legislation emanating from that assessment can be *specifically* directed towards governing *known* threats, and can thus be described as *preventive* action. Accordingly, legislative responses to scientifically-determined risk can be designed so as to manage the precise nature and scope of its expected impact. Measures adopted in line with the precautionary principle, however, operate to curb the effects of an uncertain and undefined threat before scientific assessment has established, by statistical means, its frequency and magnitude.

Having shown that the significance of the division between scientific uncertainty and scientific certainty in risk assessment lies in its capacity to determine whether precautionary or preventive action is taken, it can be said that scientific means of risk analysis are inherently incompatible with the ethos of precaution. At the crux of the matter is the degree to which the formal discourse of science and the notion of precaution consider the unknown to be captured by scientific prediction. The conflict between the precautionary principle, on the one hand, and scientific risk assessment, on the other, is the product of their conflicting perceptions of the future. Whereas the precautionary principle is founded on the understanding that science is not always capable of articulating the future, scientific risk assessment is a procedural manifestation of the notion that it is always possible to express the future in certain terms, provided that similar events in the past can be used to aid prediction. In other words, the distinction lies in the extent to which they accept that the future is foreseeable. Here it is worth bearing in mind Beck's in/calculability distinction and Jonas' theory of responsibility referred to in Chapters Eight and Nine.

12.1 Habermasian model of legitimacy

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The interface between scientific certainty and anticipatory methods of controlling the future was particularly evident in the legislative response to risk during the BSE crisis. Measures aimed at abating the spread of disease reflected the notion that law derives legitimacy from science. Here, reference is made to Habermas' schema of the *rational society* in which a pre-scientific stage of communication is a precursor to the

'scientization' of what are essentially political decisions.¹ Using Habermas' theory as its starting point, this section shows that early legal responses to BSE in the UK were based on 'post-scientized' knowledge of the disease, and as a result were predominantly *reactive* in nature. From this perspective, it can be said that legislation designed to control the potential threat of human transmission was preventive, rather than precautionary. In order to acquire legitimacy, the legislative response to human health implications necessarily mirrored *scientized* conclusions – that is, evidence obtained by scientifically-authoritative means – about BSE.

Habermas explains that the traditional dependence of the expert on the politician has reversed itself.² Accordingly, the politician becomes "the mere agent of a scientific intelligentsia",³ creating a situation in which the politician is left with nothing but a 'fictitious' decision-making power.⁴ He claims that the principles of modern society are structured in such a way that they serve as conceptual instruments for the domination of nature, and, citing Marcuse, he argues that this domination:-

"perpetuates and extends itself not only through technology but *as* technology, and the latter provides that great legitimation of the expanding political power, which absorbs all spheres of culture."⁵

By demonstrating the impossibility of the autonomy of human life, technology provides "the great rationalization of the *un*freedom of man".⁶ The submission of human life to technology that increases productivity of labour and improves the standard of living is perceived neither as irrational nor as political. Rather, the fusion of technology and domination protects and promotes the legitimacy of scientific supremacy.

¹ Habermas, J. Toward a Rational Society: Student Protest, Science and Politics (Heinemann Educational; London; 1971) Chapter 5, see in particular pages 62-63.

 $[\]frac{2}{3}$ *Ibid.* at page 63.

³ Ibid.

⁴ Ibid.

⁵ Marcuse, H. One-Dimensional Man: Studies in the Ideology of Advanced Industrial Society (Beacon Press; Boston; 1964) as cited by Habermas, J. (1971) at page 84.

⁶ *Ibid.*, emphasis added.

It follows that an understanding of Habermas' theory of scientization is imperative in the study of legislation during the BSE crisis. By examining the Government's legislative response to the epidemic, it becomes apparent that the legal measures adopted are symbolic of *post*-scientized, or scientifically *certain*, knowledge. Consequently, legislation can be described as preventive – despite the fact that the emergence of BSE was the ultimate test-bed for the precautionary principle. However, because the threat of the transmissibility of BSE to humans was framed as a *scientifically certain risk*, legislation was directed as specific and known danger. Essentially, the application of the precautionary principle was circumvented by the marginalisation of uncertainty.

A significant feature of the legal response of the UK Government to BSE is that it starkly contrasts with the approach adopted by the EC. Whereas legislation in the UK was largely reactive, the EC engaged in precautionary and *pre*-scientific risk management. By juxtaposing UK and EC tactics in the handling of BSE, it becomes clear that the operation of the precautionary principle is wholly dependent on its relationship with science and scientific risk assessment. As this section shows, UK legislation during the BSE crisis fell outside the working definition of the precautionary principle solely because it was formulated to offset a scientifically-known risk. Conversely, legislation implemented at EC level was indicative of the view that the mere possibility that BSE could transmit to humans rendered legal intervention necessary before scientific assessment could quantifiably define the likely impact of the disease. To that end, EC institutions utilised the precautionary principle as a medium through which concerns about the safety of British beef could be validly expressed.

12.2 Chronological summary: assessing the relationship between legislation and precaution/prevention

The following chronological account begins in 1988, marking the passing of the first piece of UK legislation dealing with potential human health implications of BSE. This section goes on to introduce and summarise the main programme of legislation introduced in the UK between 1988 and 1996 designed to protect the public from any

possible risk of exposure to BSE, pending its eradication. The legislation referred to here tended only to apply in England, Wales, and Scotland. Separate legislation was introduced in Northern Ireland, and in most cases it was identical to provisions implemented in the rest of the UK. Measures in England, Wales, and Scotland were adopted by means of secondary legislation under the Animal Health Act 1981, the Food Safety Act 1990, the Agriculture Act 1970, and the European Communities Act 1972. In Northern Ireland, secondary legislation was established pursuant to the Diseases of Animals (Northern Ireland) Order 1981, the Food Safety (Northern Ireland) Order 1991, the Food Order (Northern Ireland) 1989, and the Agriculture Act 1970.

The Bovine Spongiform Encephalopathy Order 1988⁷ was introduced on 21 June 1988, with the exception of article 7, which came into force almost a month later. Its primary aim was to protect animal health, and this was evident in its provisions requiring the classification of BSE as a notifiable disease⁸ and the isolation of BSE suspects when calving.⁹

In relation to the possible human health implications of BSE, the most significant provision in the 1988 Order was article 7 which prohibited the sale, supply, and use of ruminant feedstuffs that is known to, or believed to, contain ruminant-derived protein. The ban (also known at the 'ruminant feed ban') took effect from 18 July, and was to apply until the end of December 1988 while a review of rendering processes was undertaken. It was introduced, as soon as the 'feed-borne' hypothesis had been established, to prevent further transmission of BSE via human consumption. During a meeting held in May 1988, the MAFF Parliamentary Secretary to the Commons confirmed that "the aim of the proposed order was to suspend the use of animal products in meat and bonemeal used in cattle feed, as this appeared to be the source of BSE."¹⁰ In a submission to the Minister, Mr Rees acknowledged that there was evidence to reinforce the validity of the feed hypothesis, stating that:-

⁷ S.I. 1988 No.1039.

⁸ Article 4.

⁹ Article 6.

¹⁰ YB88/6.2/3.1.

"[t]he Chief Veterinary Officer is satisfied from the information produced by the investigating teams that the source of the transmissible agent which has caused BSE is through meat and bone meal derived from sheep material in which the rendering process has failed to inactivate the scrapie agent. Affected sheep material is continuing to be processed and it must be assumed therefore that cattle continue to be exposed to infection."¹¹

The issue here is the *timing* of the introduction of the 1988 Order. Despite the fact that MAFF officials were aware of BSE in November 1986, it took a further 19 *months* for the Government to take legislative action. This alone suggests that Government failed to endorse the precautionary principle in its legislation. Indeed, the lapse between the initial identification of the disease and the decision to implement legal measures to control the spread of disease and reduce the chances of human transmission is itself indicative of risk prevention rather than precaution. It seems that the general view between 1986 and 1988 was that BSE posed a hypothetical risk that was so unlikely to materialise that anticipatory precaution was unnecessary.¹² The administration of disease control was structured in such a way that scientific certainty was deemed to be a prerequisite to decision-making and the formation of policy and legislation. And, given that the benchmark of certainty was regarded as being fundamental to the management of BSE, the existence of a mere hypothetical risk was not enough to instigate any form of legislative response. In his witness statement, Dr Richard Kimberlin noted that:-

"[i]n 1988 and early 1989 we were faced with a number of uncertainties. It is understandable that it should be suggested that in such circumstances it would be better to 'err on the side of safety' and I accept that point of view as a general principle. But to be governed solely by that approach, without due consideration, creates the danger that ill-conceived protective measures will be advanced, which would in my view by unacceptable. Any recommendation must be based on science and logic."¹³

¹¹ YB88/5.6/3.3.

¹² The Inquiry into BSE and Variant CJD in the United Kingdom (HMSO; London; 2000) Volume 6, at paragraph 8.201.

¹³ Witness statement 95C, at paragraph 20.

In other words, without any evidence that there was a real risk that BSE would infect humans, the Government was of the opinion that precautionary measures were superfluous. The full thrust of this anti-precautionary stance arose from fear that such measures would unduly increase public consciousness of risk and cause unwarranted injury to the agricultural industry. It is interesting that, despite the fact that MAFF was responsible, in part, for the public health implications of animal disease, the Ministry placed its duty to defend commercial interests at the forefront of its agenda. It is true that the implications on the cattle industry of a precautionary legislative response to BSE were potentially colossal.

This combination of post-scientized decision-making and MAFF's commitment to safeguarding of trade in British beef entirely removed the option of precautionary responses from decision-making. Mr Stephen Crampton of the Consumers in Europe Group observed that "[t]he term 'precautionary principle' was not to the best of our recollection one that was used in 1990."¹⁴

Yet, in spite of the envisaged repercussions of precautionary measures, the course of events up until 1996 is testimony to the argument that the BSE legislation lacked the critical foresight necessary to avoid the full scale of the disease's eventual impact.¹⁵ The Phillips Inquiry states that, had it not been for the Government's failure to implement anticipatory provisions, "later chapters of the BSE story would have made much happier reading."¹⁶ Naturally, with hindsight, it is easy to make accusations that the Government *should have* taken action before it did. However, the argument here is that, in view of the fact that scientific uncertainty was acknowledged almost immediately after pathological analyses had discovered BSE, the precautionary principle should have come into play and anticipatory measures adopted long before June 1988. There can be little doubt that, from the outset, the Government failed to frame the 'BSE problem' in terms of uncertainty, instead opting to impose the archetype of scientific certainty and requirements of proof. Rather than accepting that the cause and nature of BSE were unknown, simple statements of 'risk' were made, masking factors such as the incomplete knowledge and understanding of the dynamics

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¹⁴ Witness statement 244, at paragraph 15.

¹⁵ BSE Inquiry (2000) Volume 3, at paragraph 4.3.

¹⁶ *Ibid.* at paragraph 4.2.

of the disease, inadequate consideration of underlying assumptions and uncertainty, and the failure to account for individual perceptions and values in the decisionmaking process. This disregard for uncertainty can be described as a consequence of the entrenchment of scientific ideology in law.

The following legislative provisions demonstrate the centrality of science in the legal handling of BSE. The introduction of legislation was prompted by scientific evidence, and the scope of legislative provisions was determined by scientific knowledge. The upshot was a range of legislative initiatives, aimed at ascertained risk and dealing in absolutes. Legislation evolved from an ethos of reason and rationality, instigating the scientization of what was, essentially, political and value-laden decision-making. This obvious tension between the scientific underpinnings of legislation and the inability of scientific assessment to calculate a definite risk with confidence runs to the core of the BSE episode. As a result of the inability of science to produce any credible quantitative risk assessment of the transmissibility of BSE, the Government embarked upon a legislative campaign, explicitly subscribing to notions of 'sound science', which created a false appearance of accuracy, control, and expertise.

As a result, legislation came to be perceived by MAFF as a major tool in bolstering consumer confidence and reassuring the public that all plausible eventualities were known and regulated. Conversely, precautionary measures were rejected for fear that they would give rise to the disclosure of scientific uncertainty, which would in turn generate a hostile consumer response and, more generally, public distrust of the Government's management of BSE. The significance attributed to the maintenance of consumer confidence, as well as the vigour of the beef export industry, led to the fallacious translation of uncertainty into the language of 'risk', 'scientific expertise', and 'legitimacy'. Although it was institutionally recognised within MAFF that, in areas where the magnitude and scale of risks are unknown, the precautionary principle should apply before exposing the public to unknown hazards that may be beyond its control,¹⁷ the Government took the line that the authority of scientific knowledge made it applicable to realms beyond realisation. The legitimacy assumed by formal

¹⁷ Witness statement 554, at page 6.
discourses of science became an invaluable asset to the Government's programme of reassurance.

The passing of the Zoonosis $Order^{18}$ and the Bovine Spongiform Encephalopathy $Order (No.2)^{19}$ in December 1988 illustrate the excesses of 'scientism' and the operation of the rhetoric of risk. It is fundamental that both provisions were founded on the belief that scientific evidence had established that the risk of human transmission to humans was remote.²⁰ Article 3(1) of the Zoonosis Order identified that BSE was a 'risk' within the meaning of section 29 of the Animal Health Act 1981.²¹

The Bovine Spongiform Encephalopathy Order (No.2) revoked and re-enacted the provisions of the Bovine Spongiform Encephalopathy Order 1988 (the 'principal Order'), and its aims were two-fold. First, it was directed at protecting animal health by prolonging the ruminant feed ban, and second, it endeavoured to safeguard public health by prohibiting the use of milk from suspected BSE-infected cattle for any purposes other than feeding to the cow's own calf. Indeed, the only substantial change to the principal Order was the article 9 the inclusion of prohibitions on (i) the sale and supply for human consumption or for feeding to animals or birds of any milk from a bovine animal which is affected or suspected of being affected with the disease;²² (ii) the use of any such milk in the manufacture of any product for sale or supply for human consumption or for feeding to animals or birds;²³ and (iii) the feeding (subject to certain exemptions) of any such milk to animals or birds.²⁴

It is interesting that, despite the fact that the Government made repeated claims that the 1988 provisions exhibited an unnecessarily high level of prudence and precaution, they were only introduced *after* it had been scientifically established that particular action was required. The milk prohibitions contained in article 9, for example, were

¹⁸ S.I. 1988 No.2264.

¹⁹ S.I. 1988 No.2299.

²⁰ See, for example, *Hansard* 1988 H.C. Oral Answers Col. 864 (1 December 1988).

²¹ Section 29 of the Animal Health Act 1981 confers powers upon Ministers to make an order designating any such disease which, in their opinion, poses a risk to human health.

²² Article 9(1)(a).

²³ Article 9(1)(b).

²⁴ Article 9(2), subject to article 9(3).

only introduced when there was evidence to suggest that there was a "greater possibility for infectivity to pass into milk".²⁵ Similarly, the Bovine Offal (Prohibition) Regulations 1989²⁶ came into force once there was scientific evidence that certain parts of bovine tissue were likely to pose a threat if they entered the human food chain. The Regulations prohibited the use of certain specified bovine offals (SBO) in human food following "clear scientific advice"²⁷ that the ban on the use of the brain, spinal cord, the spleen, the thymus, the tonsils, and the intestines of bovine animals aged six months or older was necessary.

In response to scientific evidence that the host range of BSE was wider than initially anticipated, the Bovine Spongiform Encephalopathy (No.2) Amendment Order 1990²⁸ was introduced to extend the ban on the use of SBO to cover all animal feed. It is significant that, on the basis of SEAC's recommendations, the remit of the Order was limited to the protection of animal health. SEAC had concluded that the experimental transmission of BSE to a pig did not provide evidence that the disease was capable of infecting humans. In its report, SEAC categorically stated that "[t]here were no new implications for human health in the fact that a pig had shown itself susceptible under laboratory conditions."²⁹ It went on to note that:-

"[s]ince this result shows that pigs can get spongiform encephalopathy, even though there is no evidence that they have done so in the field, we believe that pigs should no longer be fed with protein derived from bovine tissues which might contain the BSE agent, i.e. those 'specified' bovine offals that are already excluded from human consumption. It would make sense to extend this prohibition to feed for all species, including household pets, as other species have now developed spongiform encephalopathies."³⁰

This post-scientific approach to legislative action highlights the reactive, as opposed to proactive, nature of the provision.

²⁵ YB88/3.10/2.1.

²⁶ S.I. 1989 No.2061.

²⁷ 89/11.1/1.1.

²⁸ SI 1990 No.1930.

²⁹ YB90/9.07/1.4.

³⁰ YB90/9.20/10/2.

The Bovine Offal (Prohibition) (Amendment) Regulations 1994 extended the ban on the use of SBO in human food to include the intestines and thymus of calves under six months of age. When the SBO Regulations were initially drafted between June and November 1989, there was no scientific evidence to suggest that the offal from calves aged under six months posed any risk to human health. However, in June 1994, a MAFF-funded pathogenesis experiment detected BSE in the intestines of calves that had been fed infected tissue at the age of four months.³¹ This development in the knowledge and understanding of BSE instigated an immediate response, and the Regulations, as amended, broadened the definition of 'SBO' to include the intestines of an animal, aged six months or under, which had died or been slaughtered in the UK.³²

Likewise, the Specified Bovine Offal Order 1995³³ was a response to evidence of an increase in the host range for BSE³⁴ and advances in the scientific understanding about the amount of infectious material sufficient to cause infection.³⁵ The Order established tighter controls in relation to the handling of SBO, prohibiting the removal of brains and eyes, stipulating that the *whole* skull had to be disposed of as SBO, and prohibiting the removal of spinal cord from vertebral column. In contrast to the notion of precaution, legislation pertaining to the threat of BSE repeatedly trailed behind the scientific analyses that legitimised its existence, introducing safety measures to prevent a scientifically-ascertained risk. Even eight years after the first piece of BSE-related legislation was introduced, provisions continued to be formulated on the back of scientific evidence. Despite the fact that, as soon as BSE had been identified, neither its nature nor its potential impact were scientifically certain, it took the Government until 20 March 1996 to introduce emergency control measures prohibiting that sale of any meat from bovine animals for human consumption,³⁶ pending a more targeted approach to the protection of human health.

³³ S.I. 1995 No.1928.

³¹ YB94/6.17/1.1.

³² Regulation 3(b) of the Bovine Offal (Prohibition) (Amendment) Regulations 1994.

³⁴ BSE Inquiry (2000) Volume 6, at paragraphs 5.250-5.262.

³⁵ *Ibid.* at paras 5.263-5.264.

³⁶ Beef (Emergency Control) Order 1996 S.I. 1996 No.961.

12.3 Tracing the relationship between law and science

Although by the time BSE was first identified in 1986, the precautionary principle was well-established concept of environmental and health protection in UK law and policy, the legislative responses to the disease can be described as preventive rather than precautionary.³⁷ It is therefore surprising that the adoption of legislation designed to control the risk of BSE was postponed until it had scientific backing. However, although the working definition of the precautionary principle stipulates that action should be taken before scientific certainty is available, a brief exercise in uncovering the rationale behind the inter-relationship between scientific knowledge and the law sheds some light on the scientific underpinnings of BSE-related legislation.

According to McEldowney, the affiliation between science and law stems from an unparalleled combination of circumstances during the development of English law. Central to his theory is the argument that the emergence of statistical studies in the seventeenth century³⁸ bridged the gap between law reform, social science, and science in the formal sense of the word. Furthermore, he traces the evolution of the common law, noting that its rule-bound fashion and heavy reliance on analytical methods of problem-solving resulted in a display of characteristics more often associated with the principles of mathematics, and was formed using a deductive system of reasoning.³⁹ To a large extent, these attributes are portrayed by Blackstone's legacy that English law is "a science which distinguished the criteria of right and wrong".⁴⁰ It is this early association of the law with empiricism that underpins the association between law and standards of scientific proof. The development of case law reflected attempts at systematising legal responses to comparable social problems – evident from the

³⁷ See policy documents explicitly citing the 'precautionary principle': The 12th Report of the Royal Commission on *Environmental Pollution: Best Practicable Environmental Option* (HMSO; London; 1988) page 11, at paragraph2.30; HSE Discussion Document, *Generic Terms and Concepts in the Assessment and Regulation of Industrial Risks*, 30 June 1995 (HMSO; London; 1995) page 31, at paragraphs 66-67; Interdepartmental Liaison Group on Risk Assessment, Use of Risk Assessment Within Government Departments (HMSO; London; 1996) page 5, at paragraph9.

³⁸ Petty, W. and Graunt, J. (Kelley, A. M. (ed)) Natural and Political Observations on the Bills of Mortality (Fairfield; New Jersey; 1986).

³⁹ McEldowney, J. 'The Environment, Science, and Law' (1998) 1 Current Legal Issues 109-127, at page 112.

⁴⁰ Blackstone, W. Commentaries on the Laws of England Vol. X (University of Chicago Press; Chicago; 1979) at pages 5-6.

notion of stare decisis and the doctrine of precedent which are founded on the application of judicial reasoning by analogy with similar facts. McEldowney notes that "[t]echnical and formal rules, applied in an analytical and scientific way, rooted the common law to the empiricist tradition and the logic of the judges."41

Although it is true that modernity has placed new demands on environmental law to develop means of taking anticipatory action, the dependence of the law on scientific evidence continues to determine both the nature of legislative initiatives, and the point in time at which they take effect. McEldowney remarks that:-

"[w]ell-publicized problems such as acid rain, global warming, depletion of the ozone layer, and loss of biodiversity are examples of scientific research explaining the nature and scope of anthropologic impacts on the environment. Scientific data and analysis provide us with an understanding of the environment. In fact, only rarely do environmental problems not depend on some scientific explanation."42

Yet, whilst it is important that science plays an important part in defining the environment and environmental threats, it is equally important to recognise that, for as long as the formal discourse of science continues to dominate analyses of potential risks, the precautionary principle is inoperable. The crux of the matter is the degree to which the scientific discourse presides over methods of prediction. As the following section illustrates, legislative initiatives adopted by the EC during the BSE crisis were more precautionary than preventive - not because risk analysis in the EC was antiscientific in its approach, but because risk assessment reflected the notion that definitions of risk were inclusive and relative.

The EC dimension 12.4

Unsurprisingly, given its commitment to achieving the internal market, early legal responses introduced by the EC focused primarily on establishing procedures for trade

⁴¹ McEldowney, J. (1998) at page 112. ⁴² *Ibid.* at page 109.

in animals and animal products. Directive 89/662/EEC,⁴³ for example, required that veterinary checks be conducted by the 'state of dispatch' to assess the health of live animals transported between Member States, replacing veterinary checks at the Community's internal frontiers. An amending act, Council Directive 92/118/EEC,⁴⁴ set out rules for the treatment, storage, and documentation of animal products. Moreover, it introduced the concept of the 'real risk' of the spread of transmissible diseases – which was later relied upon by the Commission to justify its export ban on British cattle and beef. According to article 10(4) of the Directive:-

"[t]he decisions ... [governing trade and imports] must be taken on the basis of evaluation and, if appropriate, the opinion of the Scientific Veterinary Committee, of the *real risk* of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease or become a focus of disease or a risk to public health."⁴⁵

This extract is particularly useful because it suggests that the Directive conceived risk assessment as more than just a technocratic exercise.

Commission Decision 94/474/EEC⁴⁶ prohibited the export from UK to other Member States live cattle aged more than six months and offspring of cows which might have been infected with BSE. These trade rules were supplemented by more detailed measures concerning the preparation of meat and cattle-feed, such as the trimming of meat from BSE-infected herds to remove tissue that might contain diseased protein, prohibiting the export of offal, and specifying that protein from cattle is not to be included in cattle-feed.

⁴³ Directive 89/662/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and produce with a view to the completion of the internal market [1990] OJ L224/29, 18 August 1990.

⁴⁴ Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products etc. [1992] OJ L62/49, 15 March 1993.

⁴⁵ Directive 92/118/EEC Article 10(4), emphasis added.

⁴⁶ Commission Decision concerning certain protection measures relating to bovine spongiform encephalopathy and repealing Decisions 89/469/EEC and 90/200/EEC [1994] OJ L194/96, 29 July 1991, as amended by Commission Decision 95/287/EC [1995] OJ L181/40, 18 July 1995.

A week after the UK Government enacted the Bovine Spongiform Encephalopathy (Amendment) Order 1996, and following the release by SEAC of new scientific evidence of a causal link between BSE and CJD, the European Commission adopted Decision 96/239/EC,⁴⁷ banning the export of British cattle, beef, and beef products, such as gelatine, semen, and tallow. The risk of contracting CJD from BSE-infected meat was assessed by the Scientific Veterinary Committee of the European Union,⁴⁸ and, although the Committee concluded that it was not possible to prove that BSE was transmissible to humans, there was a 'real risk' that there *may* be human health implications. The fifth recital of the preamble to Decision 96/239/EC provided that:-

"[w]hereas, under current circumstances, a definitive stance on the transmissibility of BSE to humans is not possible; whereas a risk of transmission cannot be excluded; whereas the resulting uncertainty has created serious concern among consumers; whereas, under the circumstances and as an emergency measure, the transport of all bovine animals and all beef and veal or derived products from the United Kingdom to the other Member States should be temporarily banned; whereas the same prohibitions should also apply to exports to non-Member countries so as to prevent deflections of trade."⁴⁹

There can be not doubt that the approach adopted by the Community is profoundly different reaction to BSE. Evidence shows that, not only did the EC consider that precautionary action was vital in minimising its impact, but it also reveals a deeprooted recognition that the notion of 'risk' is as much about values as it is probability. In contrast to the traditionally-held view that no evidence of risk amounted to 'no risk', EC provisions reflect the notion that science should *inform*, but not *make*, precautionary decisions. Furthermore, they suggest that EC policy focused primarily on solutions rather than diagnosis. Instead of having the risk analysis of existing knowledge as its principal focus, EC measures are indicative of a far more flexible,

⁴⁷ Commission Decision 96/239/EC on emergency measures to protect against bovine spongiform encephalopathy [1996] OJ L78/47, 27 March 1996; Article 1, as amended by Commission Decision 96/362/EC [1996] OJ L139/17, 12 June 1996 which lifted the ban on bovine gelatine, semen, and tallow because scientific evidence suggested that they were safe.

⁴⁸ as required by Directive 92/118/EC [1992] OJ L62/49, 15 March 1993.

⁴⁹ Commission Decision 96/239/EC on emergency measures to protect against bovine spongiform encephalopathy [1996] OJ L78/47, 27 March 1996, fifth recital.

holistic, and forward-looking approach to uncertainty. They were explicit about the uncertainty with which BSE presented itself, and placed a greater premium on acting in response to credible early warnings as opposed to achieving scientifically-certain information before intervening.

12.5 Determining whether Habermas' model might be applied to the EC response to BSE

It is interesting that the UK and EC responses to BSE should be so different. Given that Habermas' model of scientization has been presented as an explanation for the overt reliance of UK legislation on scientific expertise, it is perhaps surprising that this model does not obviously apply to the EC approach. There are two possible explanations for this: either the process of scientization *did* occur in the EC, but Directives were based on fundamentally different science to UK provisions thus resulting in incompatible conclusions about the risk of BSE; or, scientization did not apply in the formation of the EC legislation in question. An examination of case law in the European Courts is useful in determining the most likely rationale for such strikingly different legislative responses to BSE.

In July 1996, the ECJ observed that Commission Decision 96/239 EC on emergency measures to protect against BSE was based unequivocally on the scientific advice of independent bodies such as SEAC and the Scientific Veterinary Committee of the European Union. In particular, the Court noted that in the light of the Veterinary Committee conclusion that, on the basis of available information, it was not possible to prove that BSE was transmissible to humans,⁵⁰ Decision 96/239 EC was both a proportionate and legitimate measure.⁵¹ The mere fact that human transmissibility posed a *potential*, albeit inconclusive, danger justified protective measures taken in pursuit of the protection of public health. And, despite having been framed as a

⁵⁰ Case C-180/96 R, United Kingdom of Great Britain and Northern Ireland v. Commission of the European Communities, European Court Reports 1996 page I-03903, at paragraph 17; see Report from the Scientific Veterinary Committee on the Potential Risk of Transmission of BSE to Humans and Animals from Bovine Colostrum, Milk and Milk Products, VI/8197/96 Version J (Final), at page 28.

⁵¹ C-157/96, The Queen v. Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex parte National Farmers' Union, European Court Reports 1998, page I-02211, at paragraph 73.

response to the lacking definitive stance on the transmissibility of BSE,⁵² it is clear both from the ECJ judgment and the Commission Decision contents that the measure was founded on scientific findings.⁵³

Following from the recognition that EC measures were fundamentally rooted in science, it is useful to turn the legal basis of legislation at UK and EC levels. A comparison of the provisions conferring powers upon the UK Government and the EC Commission to adopt respective protective measures illustrates that the disparity in the interpretation of scientific findings can perhaps be explained by differences in the legal basis of UK and EC legislation. Underpinning measures taken in the UK, section 29 of the Animal Health Act 1981 provides that:-

"the Ministers may by order designate any such disease or organism which in their opinion constitutes such a risk"

Whereas section 29 of the Animal Health Act 1981 is explicit in its mention of risk, the legal basis of measures taken by the EC are more broadly formulated in terms of the protection of human health. Decision 96/239 EC, for example, was introduced using powers deriving from Articles 3(o), 129, and 174 of the EC Treaty. Article 3(o) provides that Community objectives include the 'contribution to a high level of health protection'. Article 129 requires that the Community ensures that a high level of protection is maintained,⁵⁴ and that health protection forms a constituent part of other EC policies.⁵⁵ Furthermore, Article 174 demands that Community policy pursues the objective *inter alia* of protecting human health⁵⁶ and is based on the principles of preventive action, precaution, and polluter-pays.⁵⁷ In short, a distinction is made here between the narrow risk-based approach of section 29 and the wider scope of EC health protection requirements. Whereas under Animal Health Act 1981 the general powers of Ministers to make orders and authorise regulations is limited to situations in which there is a clear risk to human health, provisions of the EC Treaty are framed

⁵² Preamble to Decision 96/239 EC, fifth, sixth and seventh recitals.

⁵³ See minutes of Council meeting held on 1-3 April 1996, Luxembourg, in which it was held that EC measures were based on 'the best available scientific evidence' (at paragraph 1).

⁵⁴ Article 129(1) EC Treaty.

⁵⁵ Article 129(3) EC Treaty.

⁵⁶ Article 174(1) EC Treaty.

⁵⁷ Article 174(2) EC Treaty.

in such as way that powers are conferred for the adoption of measures in pursuit of the protection of human health, irrespective of whether a risk is said to exist. Although this semantic distinction might on the face of it appear to be insignificant, it is at least evidence that the framing of UK and EU legislation was inevitably going to differ as a result of their noticeably distinct origins. Reference to the term 'risk' by the Animal Health Act, in conjunction with the proviso that only those hazards that are deemed by Ministers to pose a risk fall within the scope of section 29, reinforces the notion that expert constructions of risk rank above all others. The practical implication of this sentiment is that the 'objective' findings of scientific analysis defeat subjective interpretations of risk.

By virtue of this specific phrasing of section 29, it was perhaps unavoidable that legislative measures in the UK relied so heavily on allegedly scientifically-certain predictions. By contrast, Article 174 of the EC Treaty is broader in its approach to the protection of human health, and the absence of the requirement that a risk must exist before action can be taken lends itself to a more explicit dialogue of scientific incertitude. In this respect, the EC Treaty provisions underlying legislative responses to BSE can be described as enabling the operation of precaution. Conversely, section 29 of the Animal Health Act 1981 can be understood as being the antithesis of a precautionary approach by virtue of its restriction to situations which are deemed by Ministers to constitute a risk.

Aside from the linguistic distinction between the legal basis to UK and EC legislation, their divergent approaches to BSE might also be explained as a symptom of the different administrative role adopted by the UK Government and EC institutions. Whereas a model of 'European governance'⁵⁸ ensures the fair treatment of Member States, providing a means of arbitration between different interests and securing the fulfilment of Treaty provisions, the exercise of powers at UK level is, as expected, directed at protecting domestic welfare. EC institutions during the BSE crisis, therefore, were concerned with safeguarding consumer interests at an inter-State level, whilst the principal focus of the UK Government was confined to the national export

⁵⁸ Wincott, D. 'Looking Forward or Harking Back? The Commission and Reform of Governance in the European Union' (2001) 39(5) *Journal of Common Market Studies* 897-911 at page 898; see also Commission of the European Communities, *European Governance: A White Paper*, COM (2001) 428 Final (EC Commission; Brussels; 25 July 2001) at page 8.

industry and the health impact on UK citizens. Thus, cost-benefit analyses undertaken at EC level necessarily demanded a consideration of a wider range of diverging perceptions of risk than those conducted in the UK.

It follows from a comparison of the scope of section 29 and Article 174 EC Treaty that the EC legislative approach to BSE did reflect the Habermasian model of scientization – although it adopted a broader interpretation of scientific 'risk' than the UK during the administration of BSE. The EC response was clearly mindful of the state of scientific knowledge in relation to the potential threats of BSE to human health, although, unlike the UK approach to risk assessment, it was rather more explicit about uncertain information, contradictory advice, and gaps in knowledge. It can be said that whilst the EC scheme of legislation was undoubtedly based on scientific interpretations of the risk posed by BSE – thus conforming with the theory of scientization - it also paid heed to the broader socially-informed claims that scientific claims of 'low' or 'remote' risks were essentially unsubstantiated. By acknowledging that scientific knowledge was incomplete, EC institutions were able to adopt legislation in a manner that was more consistent with the ideals of the precautionary principle. This brings to attention an critical aspect of precaution in relation to BSE. It suggests that taking 'precautionary action' is not simply a matter of taking earlier action than prevention; it is also a matter of creating a dialogue that allows for an unreserved expression of scientific uncertainty.

The following section supports the contention that in situations in which neither the nature not scale of an impending hazard is known, decision-making would be better served by focusing on the unknowns rather than constructions of the future based on very loosely similar pasts. This section offers a theoretical argument as evidence that, although the rhetoric of risk was critical to the marginalisation of uncertainty and maintaining scientific supremacy, the application of formal risk assessment to BSE was a futile exercise.

12.6 The bureaucracy of risk

"Uncertainty is present in the decision-making process, not so much because there is a future as that there is, and will be, a past ... We are prisoners of the future because we will be ensnared by our past."⁵⁹

Indeed, the handling of the risk posed by BSE exposes the limitations of traditional forms of risk modeling. In order to demonstrate the shortcomings of conventional assessment, this section conceptualizes events during the BSE episode in a theory called 'the bureaucracy of risk'. In doing so, it draws heavily on the works of Bernstein, Knight, Keynes, and Hacking.

In his comprehensive study of the notion of 'risk', Bernstein captures the fundamental problem of prediction, stating that:-

"The information you have is not the information you want. The information you want is not the information you need. The information you need is not the information you can obtain. The information you can obtain costs more than you want to pay."⁶⁰

In recognizing that risk assessment procedures are continually faced with incomplete knowledge from which to extrapolate an understanding of the future, he notes that uncertainty is an inescapable reality of the process of prediction. Central to Bernstein's theory is the notion that risk assessment is a means of "putting the future at the service of the present."⁶¹ And, given that the future is incomprehensible until it has manifested itself as the present, the only way in which they determine the future is by consulting the past. For him, the issue boils down to the extent to which the past can determine the future. He notes that:-

⁵⁹ Dixon, R. 'Uncertainty, Unobstructedness, and Power' (1986) 8(4) Journal of Post Keynesian Economics 585-590 at page 587.

⁶⁰ Bernstein, P. L. Against the Gods: The Remarkable Story of Risk (John Wiley & Sons; New York; 1996) at page 202.

⁶¹ Ibid. at page 1.

"We cannot quantify the future, because it is an unknown, but we have learned how to use numbers to scrutinize what happened in the past. But to what degree should we rely on the patterns of the past to tell us what the future will be like? Which matters more when facing a risk, the facts as we see them or our subjective belief in what lies hidden in the void of time?"62

The practice of projecting the past into the future takes on a deeper significance in modernity because hazards are known to present themselves with increased frequency and scale. The gravity of the potential implications of BSE to human health was clearly a motivating factor in the utilization of previously observed scrapie patterns. The mere possibility that BSE *might* jump the species barrier resulted in an increased incentive to define the unknown future with discernible certitude.

Yet, in spite of the perceived benefits of certitude in the expression of prediction, past performance is "a frail guide to the future."⁶³ Simply because similar events have been observed repeatedly in the past "is a poor excuse for believing that they will probably occur in the future."⁶⁴ The incidence of surprise in reality leads Knight to describe the unknowable future as a symptom of 'the uncertainty problem'⁶⁵ He claims that a priori reasoning does not remove indeterminacy from the future,⁶⁶ and that at the root of the uncertainty problem, in economics at least, is the forwardlooking nature of the economic process itself.⁶⁷ Indeterminacy prevails because it is impossible to encapsulate the novelty with which the future presents itself using backward-looking models. Knight argues that:-

"[Any given] 'instance' ... is so entirely unique that there are no others or not a sufficient number to make it possible to tabulate enough like it to

⁶² *Ibid.* at page 6.

⁶³ *Ibid.* at page 298.

⁶⁴ Ibid. at page 226; see also Keynes, J. M. A Treatise on Probability: Exploration of the Meaning and Application of Probability (Macmillan; London; 1921) at page 407.

Knight, F. H. Risk, Uncertainty and Profit (Century Press; New York; 1921) at page 237.

⁶⁶ Bernstein, P. L. (1996) at page 220.

⁶⁷ Knight, F.H. (1921) at page 237.

form a basis for any inference of value about any real probability in the case we are interested in."⁶⁸

This sentiment was also reflected by Chesterton, in his book *Orthodoxy*, when he acknowledged that the pervasiveness of uncertainty cannot be overcome by the desire to define the future in precise terms. He noted that:-

"[t]he real trouble with this world of ours is not that it is an unreasonable world, nor even that it is a reasonable one. The commonest kind of trouble is that it is nearly reasonable, but not quite. Life is not an illogicality; yet it is a trap for logicians. It looks just a little more mathematical and regular than it is; its exactitude is obvious, but its inexactitude is hidden; its wildness lies in wait."⁶⁹

It is evident that this 'uncertainty problem' was central to the construction of risk during the BSE crisis. Juxtaposing the forward-looking nature of risk assessment with the backward-looking character of the scrapie analogy, it becomes apparent that the identification of the risk of human transmission as 'remote' was a matter of social construction rather than scientifically corroborated fact. This construction lies at the heart of the theory of the 'bureaucracy of risk'. From this perspective, the tradition of numerically characterizing the future forms part of the 'great bureaucratic machinery'⁷⁰ of risk. The appeal of defining future threats using the rhetoric of risk is that it implies a superficial neutrality in the perception of impending events.⁷¹ Their existence is presented in absolute, as opposed to relative, terms. This led Hacking to conclude that "the taming of chance by statistics does not introduce a new liberty."⁷² By employing the concept of 'risk' to define future events, the freedom to perceive the future as an unknown entity is effectively restricted. In this sense, risk is prescriptive in design, and, to that end, it is limited in its understanding of potential hazards. In fact, this is a detail that is commonly overlooked by conventional models

⁶⁸ *Ibid.* at page 226.

⁶⁹ Chesterton, G. K. Orthodoxy (Lane Press; New York; 1909) at pages 149-50.

⁷⁰ Hacking, I. 'How Should We Do the History of Statistics?' in Burchell, G. *et al.* (eds) *The Foucault Effect: Studies in Governmentality* (University of Chicago Press; Chicago; 1991) Chapter 9, at page 181.

⁷¹ *Ibid.* at page 184.

⁷² *Ibid.* at page 194.

of risk assessment is that the concept of 'risk' is a matter of choice rather than of fate.⁷³ Bernstein claims that the word 'risk' can be traced to the Italian 'risicare', which means 'to dare'.⁷⁴ And yet, traditionally, risk assessment is founded on the notion that the future imitates the past.

Keynes, in particular, is skeptical of claims that the utility of prediction derives from observations of the frequency and magnitude of past events. He claims that:-

"[t]here is little likelihood of our discovering a method of recognizing particular probabilities, without any assistance whatever from our intuition or direct judgment ... A proposition is not probable because we think it so."⁷⁵

Of course, this relativist position lies in stark contrast to the process of scientific risk assessment which claims to have an unshakable basis in norms such as objectivity, rationality, impartiality and certitude. In relation to BSE, it is argued that the uncertainty with which the disease presented itself was offset by the implementation of the formal discourse of science as a means of constructing a certain and defined risk. By employing the 'bureaucracy of risk', uncertainty came to be portrayed as an identifiable and known entity. During a House of Commons debate about the Government's reassurances that BSE posed no risk to human health, Professor Lang pointed out that the restrictive nature of scientific risk definitions excluded due consideration of its subjective and contextual elements:-

"Even if MAFF and Mr Hogg, repeating what Mr Gummer and Mr Dorrell said back in 1989 when he was Junior Minister of Health, say that beef is 100 per cent safe, I do not think that the public now believes that view. This is why I quoted earlier an opinion poll of only two weeks ago. You are essentially having promises of certainty put into a situation of uncertainty as far as the consumer is concerned ... The issue now is the

⁷³ Bernstein, P. L. (1996) at page 8.

⁷⁴ Ibid.

⁷⁵ Keynes, J. M. (1921) at pages 3-4.

psychology of risk. There is a burgeoning literature by academics that I would recommend the Committee spend some time looking at."⁷⁶

These promises of certainty were, of course, impossible to maintain. Yet, in spite of their emptiness, they were crucial in ascribing authority to scientific knowledge and upholding the concept of expertise. In this respect, the BSE case study provides an unparalleled example of hyperbolic statements of scientific certainty against a backdrop of indeterminate information and human ignorance. And, as Tickner recently argued at a conference on *Ecological Risks and Precaution in the Nordic Countries*, 'the way we do science inhibits the operation of precaution.'⁷⁷ By relying on the projection of the past into the future, scientific assessment places undue emphasis on applying what is known to what is *un*known. Furthermore, in its framing of BSE as purely a scientific problem, risk assessment simply reinforced the notion that the articulation of the future is a matter solely for expert surveillance. In his address the House of Commons in May 1990, Martyn Jones MP expressed concern over the unwarranted reliance of policy on so-called scientific expertise, stating that:-

"I do not profess to be an expert on this subject. We have had a definition of 'expert' as 'ex' being the unknown factor and 'spurt' being a little drip under pressure, and we are bandying the word about rather too much."⁷⁸

12.7 What difference would the precautionary principle have made?

The pertaining question at the end of this case study is: what difference, if any, could the precautionary principle have made? Any answer will of course require a degree of imagination, and suggestions made in the following section are in no way intended to provide a definitive retrospective solution to the BSE problem. It is not my intention to make propose an infallible model of precaution to counter the dangers posed by BSE to humans. Instead, this section makes tentative statements about the way in

⁷⁶ House of Commons Agriculture and Health Committees' Joint Report: BSE and CJD: Recent Developments HC-331 (HMSO; London; 1996) at page 127, emphasis added.

⁷⁷ Tickner, J. 'Scientific and Political Setting: Key Concepts of Precaution and Risk Assessment' at the *Conference on Ecological Risks and Precaution in Nordic Countries*, University of Oslo, 26-27 May 2005.

⁷⁸ Martyn Jones, MP, Clywd, South-West, Hansard 1990 H.C. Col.1012 (17 May 1990).

which precautionary conduct might have fitted into the complex sequence of events between 1986 and 1996.

The significance of the BSE case study lies in its illustration of the argument that problems with the precautionary principle extend beyond it definitional deficit. It has shown that the operation of a precautionary mindset is limited not only by the lacking consensus in relation to the meaning and scope of precaution, but more importantly, by the deeply-rooted institutional reliance of risk assessment on notions of 'sound science'. To some extent, it is reasonable to suggest that an overhaul in the relationship between Government decision-making and scientific knowledge – including a broadening of what is meant by 'knowledge' and 'expertise' – might induce a more precautionary approach to the future. Although this is a desirable end, it is neither a realistic nor attainable result in a political climate confronted with the judicial review of decision-making. That is to say, whilst scientific supremacy in the analysis of impending hazards presents a serious challenge to the workability of the precautionary principle, the dominance of science in risk assessment should perhaps be expected in view of the judicial review of decision-making.

The issue here is to determine when the precautionary principle might have come into effect. The critical period in which initial precautionary measures might have been called for is between November 1986 when the Central Veterinary Laboratory first identified BSE and June 1988 when the BSE Order 1988 came into effect. The following chronological account refers to the main events occurring between these two dates. It illustrates that, in the 19 months preceding the adoption of the BSE Order 1988, there was ample opportunity to implement measures consistent with the ideals of precaution. Working on the basis that the precautionary principle is triggered by scientifically uncertain threats, precautionary territory was entered into as soon as it was recognised that BSE might pose a threat, albeit uncertain, to human health. On the evidence, it appears that a potential link between BSE and human spongiform encephalopathies was first made by Raymond Bradley, Head of the Pathology Department at the CVL, in December 1986. Certainly, by June 1987 it was widely recognised within the scientific community that there were considerable deficiencies in knowledge about the nature and scope of BSE. It is therefore reasonable to suggest that a strict precautionary approach could have ensued late in

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1986; or by mid-1987 at the latest. That is not to say that an outright ban on the human consumption of infected meat should have been adopted as an immediate response to counter the scientifically uncertain threat of transmission. Instead, a discourse of precaution, recognising not only that information about BSE was inconclusive and contradictory, but also that the scope of incertitude was unknown, could have been employed almost from the outset of the crisis. The outcome would have been potentially twofold. First, the legislative control of the human consumption of infected meat – which in fact began with the introduction of the Bovine Offal (Prohibition) Regulations 1989, followed by the Bovine Offal (Amendment) Regulations in 1992 and the Specified Bovine Offal (Amendment) Order in 1995 – might have been imposed at the very early stages of the episode. Second, it is likely that a dialogue between MAFF and the public that was explicit about its limited understanding of BSE would have curbed the backlash of distrust in scientific expertise.

Brief chronology of events: November 1986 – March 1996]
November 1986	BSE identified by CVL	
19 December 1986	Head of the Pathology Department, CVL, observed that:-	
-	"[i]f the disease turned out to be bovine scrapie it would have severe repercussions to the export trade and possibly also for humans if for example it was discovered that humans with spongiform encephalopathies had close association with the cattle." ⁷⁹	BSE identified as a potential threat to human health although pathological and epidemiological characteristics were unknown. Arguably this is 'precautionary territory'.
5 June 1987	Chief Veterinary Officer warned that the disclosure of information to the public might lead to:-	
	"hysterical demands for immediate draconian government measures" ⁸⁰	

		7
	Furthermore, he noted that:-	
	"[i]n view of our very uncertain knowledge on the disorder it does not seem appropriate at this stage for MAFF to issue general information" ⁸¹	Acknowledgement of the limited understanding of BSE. The threshold of precaution has been satisfied.
15 October 1987	John Suich, MAFF Animal Health Division, comments that:- "[t]here is no evidence that it [BSE] is transmissible to humans." ⁸²	Scientific reliance on past evidence. Forming the basis of a preventative, rather than precautionary, approach.
6 November 1987	32 cases of BSE confirmed on 29 farms ⁸³	
10 November 1987	128 confirmed or suspected cases of BSE reported ⁸⁴	
13 November 1987	181 cases of BSE confirmed ⁸⁵	
20 November 1987	225 cases of BSE on 138 farms confirmed ⁸⁶	
4 December 1987	Lord Montagu of Beaulieu expresses concern about the potential human health implications of BSE:- "At the present time I understand little or no research has been done on	
- -	whether this disease can be transmitted to humans through the consumption of beef from infected animals, and, until this is known, it seems quite wrong to me that it is possible to sell infected carcasses for this purpose." ⁸⁷	Recognition of inherent uncertainty, although concerns about limited information on BSE were not incorporated into formal assessment procedures.
15 January 1988	414 cases of BSE confirmed ⁸⁸]

18 July 1988	Article 7 of the BSE Order 1988 came into effect imposing ruminant feed ban	Imposition of legislation, but only after it had been established as a matter of 'scientific certainty' that feedstuff was the most probable cause of infection.
13 November 1989	Bovine Offal (Prohibition) Regulations 1989 came into force banning the use of certain specified offals for human consumption	
12 March 1992	Bovine Offal Prohibition (Amendment) Regulations 1992 prohibited the use of the bovine head after the skull is opened in any food intended for human consumption	
15 December 1995	Specified Bovine Offal (Amendment) Order 1995 prohibited the use of the bovine vertebral column in the manufacture of all MRM and other products for human consumption	
29 March 1996	A targeted approach to the protection of human health: the Beef (Emergency Control) Order 1996 prohibited the sale for human consumption of any meat from bovine animals showing more than two permanent incisors	

The conclusion to draw here is that, had there been a more explicit dialogue about the uncertainty with which BSE presented itself, precautionary measures might have been adopted far sooner than the first legislative provision applying in relation to human transmissibility in July 1988. The implementation of legislation must be seen here as not only a measured response to scientifically-determined information about BSE, but also as an attempt, intentional or not, to reinforce scientific findings that BSE posed a negligible risk to human health. Here it is fitting to acknowledge that the decision to impose (or *not* impose, as the evidence suggests) precautionary measures must be considered in view of the fact that pressures from the cattle industry presented an enormous challenge to the Government – the task of balancing potentially catastrophic and irreversible dangers to human health against potentially disastrous implications for the agricultural sector. Of course, determining whether and when

precaution might come into play was never going to be a decision to be taken lightly. Furthermore, given the historical patterns of the scrapie agent, it was perhaps inevitable that, when presented with a broadly similar disease in cattle, MAFF was bound to draw a comparison and conclude that British beef was safe to eat. Yet, as the arguments in this thesis have shown that the application of precaution was certainly limited by the exclusive reliance on scientific assessment. If nothing else, an approach acknowledging the inadequacy of information about BSE would encourage earlier communication of scientific uncertainty and the potential implications of *un*sound science.

The role of legislation in upholding the supremacy of scientific assessment during the BSE crisis is crucial. The interaction between legislation and scientific discourse is essentially a two-way process. Not only does scientific discourse confer legitimacy upon legislation, but legislation is itself a means of conferring legitimacy upon action taken in response to risk. The practice of imposing legal provisions to control the threat of transmission can be described as having a legitimating function. The argument that law is a significant tool in the legitimation of decision-making allows for a study of the BSE episode from a distinct legal perspective.

12.8 Legislation as a means of enforcing the bureaucracy of risk

It has already been established that the application of legislation in the regulation of the human impact of BSE is important because it reveals the intrinsic relationship between law and science. The dependence of legal regulation on wholly scientific constructions of risk is problematic because it precludes a truly anticipatory approach to the future. Luhmann comments on the typical concern of a normative orientation to be able to know now what the future entails:-

"We can ... hardly expect that risk problems ... can be solved within the framework of suitable legal forms. For in the case of risks we are not dealing with a future for which we can in our present determine how others are to behave in future situations. A risk cannot be violated. If the law can be expected to assume risks, this can only occur be

detemporalizing the assessment of what is right and wrong. In other words, symbols such as legal force or legal validity have to be deployed with 'binding' effect regardless of whether the future proves a decision right or wrong."⁸⁹

Aside from the problem of the limited capacity of scientific assessment to predict future hazards, the imposition of legislation during the BSE crisis calls to mind the relationship between the law and its role in restoring public confidence in British beef. In addition to the function of scientific discourse in creating and legitimating specific perceptions of risk, a separate process of legitimation through the law was critical to the political reassurance that the spread of BSE was under control. The issue is the division between policy and law. There is a distinction - not least in implication between a rule promulgated, adopted or ratified by a Government and a rule that has been adopted as legally-enforceable. The passing of legislation in relation to BSE was a significant in that it conferred 'unconstrained normative validity'⁹⁰ on findings that the risk of human transmission was negligible. Drawing on the decisionistic model of legal theory expounded by Carl Schmitt, the process of enacting legal provisions to control the impact of BSE can be seen as creating legitimation in relation to the legislative content, but also, by extension, to the scientific opinion upon which the legislation was based. In his explanation of Schmitt's theory, Luhmann notes that:-

"[t]he positivization of law means that legitimate legal validity [Rechtsgeltung] can be obtained for any given contents, and that this is accomplished through a decision which confers validity upon the law".⁹¹

Habermas' *Legitimation Crisis* also reflects the view that formal rules of procedure provide a sufficient basis for the legitimation of a decision.⁹² He describes the notion of legitimacy as:-

"the abstract imperative validity [Sollgeltung] of norms that can do without a material justification beyond the following of correct procedure in origin and application".⁹³

Furthermore, Habermas goes on to note legal process is itself capable of establishing abstract validity, stating that:-

"legality can create legitimation when, and only when, grounds can be provided to show that certain formal procedures fulfil material claims to justice under certain institutional boundary conditions."⁹⁴

In accordance with this theory of legitimation, it is reasonable to suggest that, by virtue of strict adherence to legislative procedure, legal provisions adopted during the BSE episode had a specific legitimating function. The use of the term 'legitimation' is subtly different to the Habermasian notion. Whereas Habermas refers to legitimacy in relation to the degree to which the creation and implementation of law conforms with accepted procedure, it is used here in a broader manner to show that, by virtue of the observance of legal procedure, the content of legislation can also be regarded as 'legitimate' in the sense that it is commonly accepted and normatively valid. The point here is that, as a result of their status as formal law, measures adopted in response to BSE were effective tools in enforcing the authority of scientific evidence that the disease posed little risk to human health. In this respect, the passing of legislation represented a nexus between law and science. On the one hand (as discussed above), scientific consensus legitimizes legal measures; whilst on the other hand, the forming of legislation legitimizes the scientific arguments reflected in its provisions. Legitimation in this context, therefore, is essentially a two-way process.

Yet, whilst this understanding of the legitimating relationship between law and science is useful in that it offers an insight into the role of legislation and scientific knowledge in underpinning claims that threats to the agricultural industry far outweighed those to human health, it overlooks the fact that science is a fallible process. Scientific authority is constructed, not out of its reputation for accuracy, but out of a social hierarchy of knowledge-production in which the scientific profession lies at the top of the order. At the root of scientific supremacy is the propensity of scientific method to pledge objectivity, certainty and numerical precision in its findings. However, as Kaiser points out, the failure of science to acknowledge its limitations opens up a space for irresponsibility in decision-making. He argues, and rightly so, that:-

"[w]hen science is not self-conscious about its own potential pitfalls and shortcomings, when science assigns to itself a better track record than is justified by history, when science forgets the many idealizations and abstractions that are prerequisites for its model-building and testing procedures, and finally, when science portrays itself as unaffected by large commercial or political interests, it stands in grave danger of becoming socially irresponsible."

The precautionary principle has traditionally been presented as a retort to the growing recognition that science might not be capable of perceiving, let alone expressing, future hazards. In spite of this interpretation, the operation of precaution continues to be determined by scientific constructions of the future. The problem, therefore, with the portrayal of science and precaution as alternatives is that the application of the precautionary principle is still ultimately governed by scientific understandings of the future. And, as this thesis has shown, science, and in particular the scientific expertise that informs policy-making in environmental protection, is far more divided, pluralistic, value-based, and uncertainty than formal scientific discourse suggests.

It is fitting here to end with an optimistic vision of an effective marriage between science and precaution:-

"A truly precautionary science does not refrain from entering discussions and arenas where values and ethics are at stake, but contributes to these in a balanced and self-reflective manner. The new objectivity in science is not an attempt to stick to "hard facts" alone. It is the "hard decisions and soft facts" that pose the challenge of our times. Thus, the new objectivity of precautionary science amounts to new modes of organizing and managing research, including new forms of quality control, with the aim of providing relevant information for policy-making that only scientific method can reveal, and that can effectively contribute to a balanced picture of the various options that society has to consider. Present-day science does not in general fit this picture, but luckily it contains all the intellectual resources necessary to become precautionary science to the benefit of society and nature."⁹⁵

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Conclusion

The precautionary principle is a fascinating concept, both in its own right, and in the contexts within which it has been presented. There is little doubt that it has marked the onset of a new era in environmental protection, and has generated considerable debate - amongst both academics and practitioners - about the way in which the future is articulated and managed. Whilst the precautionary principle has been hailed as representing the most significant development in securing responsibility for potentially long-term impacts of decision-making, it has also been widely criticised for its empty definition and its paradoxical relationship with scientific risk assessment. This thesis presents the precautionary principle with particular reference to its definitional deficit, and its overt reliance on scientific means of constructing the unknown. It shows that the incongruity of its definition is reflective of its lacking normative content, which gives rise to an inescapably fluid concept whose meaning and application varies so considerably that it is impossible to isolate a single version of 'the' precautionary principle. The consequence of its inherent relativity is twofold. First, the precautionary principle is frequently the subject of litigation, meaning that judicial interpretations are often relied upon to flesh out the meaning of precaution. Second, subjective constructions of the implications of the precautionary principle generate a conceptual inconsistency with the scientific processes of risk analysis upon which its application is based.

Determining whether the precautionary principle applies in any given situation is a matter for scientific assessment. There is clear evidence of the affiliation between the operation of precaution and risk assessment at international, EC, and domestic levels. The implementation of risk assessment in this context is contingent upon there being a distinction between risk and uncertainty. It operates on the basis that risk can be quantified, but uncertainty cannot. Conventional models of risk assessment reflect the notion that, given that risk can be numerically articulated, risk predictions are *certain*. The specificity with which risk is expressed makes it an unambiguous construction of the future, and, to that end, it can be described as preserving the ideals of scientific certitude. Uncertainty, on the other hand, is hostile to specific numerical delineation.

Taking Principle 15 of the 1992 Rio Declaration as its 'working definition', it is clear that the precautionary principle applies to hazards that are scientifically uncertain. On the strength of the risk/uncertainty dichotomy, risk assessment procedures are used to establish whether it is possible to assign numerical values to impending threats. If, on reflection of past events, a future hazard is expected to transpire in a similar manner, existing knowledge is used to quantify its materialisation. The quantification of the future precludes the application of the precautionary principle because it is perceived as having been predicted with scientific certainty.

The reliance of the precautionary principle on scientific assessment raises an interesting paradox. On the one hand, the application of precautionary measures is seen as a statement that scientific knowledge is incapable of calculating the occurrence of future hazards in any meaningful sense. On the other, determining the implementation of precautionary measures is exclusively scientific in its approach. The fundamental problem here is that the ideology upon which scientific foresight is based is deeply flawed. Subscribing to the central tenets of the philosophy of science, risk assessment models endorse the notions of scientific objectivity, rationality and certitude. The legitimacy of risk predictions is secured by the procedural dependence of risk assessment on the precepts that scientific findings possess universal meaning. As a result of its deeply-embedded roots in scientific dogma, risk assessment functions on the understanding that risk is an objective concept, and that risk predictions are obtained without recourse to their social backdrop.

As this thesis has illustrated, positivist approaches to risk have been criticised for their failure to acknowledge that the concept of risk encompasses factors other than its likely magnitude and occurrence. Social constructivist theorists point out that the impact of context on risk perceptions undermines claims made by risk assessment to objectivity and certitude. In essence, science is a social process.⁹⁶ To that effect, risk is a socially-constructed concept. Whereas conventional forms of risk assessment reflect the notion that risk is an objective, linear and statistically-certain phenomenon, they overlook its incommensurability. Risk is an inherently subjective concept that can be perceived, but does not exist *per se*. Traditionally-deterministic approaches to risk assessment neglect the fact that it is impossible to reduce its multidimensional

nature into universally intelligible quantities without reference to its complex, valueladen, and non-linear aspects.

This thesis does not argue that conventional reductionist models of risk assessment have no place in policy-making relating to human health and the environment. Rather, it submits that recognition of the relativity of risk is evidence that risk estimates do not lend themselves to normative interpretation. Predictions deriving from scientific risk assessment do not convey deficiencies in its knowledge base, such as incomplete or disputed information. Consequently, risk calculations should not be construed as values that prescribe a particular course of action. By doing so, the precautionary principle is deemed to be inapplicable to hazards that have been quantified, despite the fact that their occurrence and impact are essentially unknown.

The works of social theorists such as Beck, Giddens, Luhmann and Jonas are crucial to the argument that risk in the modern era presents challenges for precaution. They focus on the part played by risk in modernity, and they make a temporal distinction between environmental hazards arising in the past and those in post-industrial society. Accordingly, hazards generated in the post-industrial modern era are essentially incalculable and uncontrollable. The uncertainty with which hazards in contemporary society present themselves makes them statistically unpredictable and uncontrollable by conventional means. Precautionary measures, therefore, become more desirable than reactive responses to risk.

The proliferation of uncertain risks in modernity is indicative of a process referred to by Beck as 'reflexive modernisation', which describes a situation in which technological and scientific progress acts upon itself and self-destructs. Modernity confronts itself as an object for reflection and undercuts its orthodox foundations. Consequently, there is a shift in the societal role of science. Whereas scientific knowledge had traditionally been looked upon as a source of rationality and expertise, reflexive modernisation has forced it to take on a new dual role. Scientific enterprise is not only a means of achieving knowledge, but it is also a channel through which existing knowledge is scrutinised. Although modernity has brought with it scientific progression, it has also drawn attention to the negative repercussions of technological advance. Despite the fact that science has traditionally been relied upon as a means of controlling future uncertainty, it has developed the capacity to generate as much uncertainty as it eliminates.

Models of scientific displacement are useful in illustrating the theory that science is incapable of producing absolute results. They serve to highlight that scientific inquiry is a dynamic process, and that scientific knowledge is continually superseded by new and more pressing problems. With particular reference to Kuhn's model of scientific revolution, it is shown that uncertainty in scientific investigation is a universal predicament. The process of specialisation stimulates the constant evaluation of existing knowledge, generating new knowledge to replace old. This displacement indicates that the validity of scientific findings is contingent upon context, and that both the accuracy and legitimacy of findings are revised with time. The natural conclusion to draw is that, since it is always subject to displacement, science is incapable of framing the future in absolute terms.

In conjunction with theories of reflexive modernisation and scientific displacement, the process of individualisation is critical to constructions of risk in the modern era. The emergence of a pluralistic society, with increased emphasis on the individual rather than the collective, has brought about the liberalisation of the individual from rigid social structures without the formation of new social structures. This demise of social control structures removes any sense of consensus, certainty and security that were traditionally associated with the industrial phase. Furthermore, and as a result of the breakdown of collective risk monitoring and control, individuals are forced to bear the unforeseen consequences of decision-making. This institutional failure to be in command of unknown future not only increases the demand for the collective identification and management of hazards, but it also fosters processes of self-criticism, reflexive modernisation and ontological insecurity.

By virtue of the incalculability of future hazards, the perpetual creation by scientific investigation of scientific uncertainty, and the disembedding of social structures traditionally used to define and extend control over risk, it is possible to conclude that risk is scientifically uncertain, in the sense that it is adverse to objective calculation. Social constructivism is useful in that it recognises the inadequacies of conventional forms of risk assessment, and provides evidence to suggest that risk is indeed a

subjectively-constructed concept. Unlike the positivist tradition, which champions principles such as realism, objectivism and rationality, the constructivist paradigm illustrates that risk is a social, rather than physical, problem. Social constructivist theorists claim that definitions of risk reflect factors beyond those represented in scientific assessment, and that the conceptualisation of risk is a subjective process that reflects social differentiations.

Yet, in spite of the shortfalls of conventional modes of risk prediction, scientific discourse continues to provide the principal means of engaging with the future. Although there are obvious practical benefits of reducing the unknown into digestible quantities, deterministic models of risk assessment are undoubtedly incapable of establishing a useful dialogue regarding the future. The BSE episode during the 1980s and 1990s provides an excellent example of the failure of scientific assessment to identify and define future hazards. Focusing on the institutional marginalisation of uncertainty, this case study shows that the rhetoric of risk and the supremacy of scientific means of prediction created what might be referred to as the 'bureaucratisation of risk'. The institutional marginalisation of uncertainty operated on two fundamental levels – first, in relation to the scientific investigation into the human health implications of BSE; and second, in relation to the political administration of the epidemic. On both counts, the threat of the transmission of BSE to humans was presented as a known and calculable risk, when in fact, there existed considerable uncertainty as to the source, nature and transmissibility of the disease.

Given that BSE was a novel disease, there was little by way of scientific information about its pathology and epidemiology. Instead of acknowledging that almost nothing was known about BSE, MAFF used models tracing the behaviour of the scrapie agent in sheep, claiming that the findings of scrapie observations could be applied to BSE because the diseases were analogous. This practice of projecting the past into the future in order to predict a course of events is crucial to scientific foresight. The argument is that, provided that past events and anticipated future events are broadly similar, the future will reflect the past. Scientists during the BSE crisis were adamant that, given that scrapie had existed in British sheep for hundreds of years and had not been known to transmit to humans, it could be said with confidence that BSE would not adversely affect human health. In relation to the political administration of the epidemic, the official stance was that BSE-infected meat was safe to eat. Repeated reassurances of safety were issued in the ten years after BSE was first identified in 1986 until the Government recognised that BSE was linked to CJD in 1996. Statements that BSE posed no, or low, risk to humans were based solely on scientific conclusions that the disease would mirror scrapie patterns. These scientific findings were accepted by the Government as categorical evidence that BSE was incapable of jumping the species barrier. Consequently, policy adopted in response to BSE reflected the belief that BSE was confined certain species, not including humans.

A study of the legislation implemented to control the impact of the draws attention to the relationship between the law and scientific certainty. Although legal measures during the BSE episode were often dressed up as upholding the concept of precaution, their reliance on scientifically-certain findings rendered them preventive, as opposed to precautionary. UK legislation was entirely reactive in nature, upholding Habermas' theory that law derives legitimacy from science and illustrating postscientized, or backward-looking, decision-making. EC provisions, on the other hand, were largely proactive in its approach, exhibiting a forward-looking, anticipatory approach.

This distinction between backward-looking and forward-looking approaches to decision-making introduces an interesting dilemma for the precautionary principle. Whilst the notion of precaution essentially requires a proactive response to impending hazards, and is an attempt at least to engage with the unknown future, scientific risk assessment looks to the past for answers, and is contingent on the establishment of scientific certainty before action is taken. The distinction, although subtle, marks the point at which the precautionary principle and scientific knowledge depart. Given that the operation of the precautionary principle is fundamentally tied to scientific analysis, it can be said that the disparity between the backward-looking nature of science and the forward-looking nature of precautionary principle.

This thesis has brought together substantial literatures relating to sociological, legal, and scientific interpretations of risk. It has shown that, despite the fact that the notion

of precaution is well recognised in the protection of human health and the environment, there is remarkably little consensus about its operation. A fundamental consequence of the definitional deficit of the precautionary principle, in my opinion, is ambiguity in relation to its point of application. This thesis has shown that, although there is some disagreement about the role of formal risk assessment in determining the operation of precaution, in practice, the application of the precautionary principle is traditionally ascertained by scientific means. This finding is evident in a case study of the BSE epidemic.

On the basis of this argument, broad conclusions can be drawn. The first is that the imposition of legal measures in the regulation of risk is heavily reliant on scientifically-verified evidence. The second is that scientific risk assessment is conceptually inconsistent with the aspirations of precaution. The third is that absolute reliance on risk assessment can limit the operation of precaution. The BSE crisis provides an excellent example of a scientific risk discourse inhibiting a more precautionary response to expected threats.

Whilst it is recognised that debate surrounding the precautionary principle will not end here, this thesis has taken steps to unite literature that is commonly presented in distinct categories. It acknowledges that the precautionary principle will continue to play an integral part in the protection of human health and the environment, but it is also mindful of its practical limitations. It endorses the precautionary principle as a central component of policy-making, but it serves as a warning that questions relating to its workability call for a consideration of far deeper issues concerning the dialogue between science and regulation.

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