Uncertainty in policy relevant sciences

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INSTITUTE OF ENVIRONMENT & RESOURCES

Uncertainty in policy relevant sciences

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Preface

The debate on the precautionary principle has highlighted the fact that effective management of the risks associated with technological development will require increased democratisation, adaptability and reflexivity in public decision making. While science will become increasingly important in addressing these risks, it will also become increasingly insufficient. Scientists & engineers participating in regulatory decision making will require new methodologies, such that the assessments they perform contribute to fostering adaptability and reflexivity in decision making. It this context, this Ph.D. dissertation illustrates a novel approach to diagnosing and communicating the uncertainty that characterises scientific assessments of complex policy problems.

Chapter 1 of this dissertation is aimed at justifying the need for new methods of uncertainty assessment. Chapter 2 presents the conceptual framework upon which the novel approach applied in this project is based, essentially examining the question: how does uncertainty manifest itself in the context of policy relevant sciences? Chapters 3 and 4 illustrate how this conceptual framework was applied through expert elicitations focusing on two different case studies related to the risk assessment of genetically modified crops. Chapter 5 offers reflections on the experiences gained in the process of applying the conceptual framework.

This dissertation was primarily written for a target audience of natural scientists and engineers involved in policy relevant sciences. The goal was to illustrate the basis for conducting uncertainty analysis in policy relevant sciences, and to demonstrate how this could be done. In addition to these natural scientists and engineers, the dissertation will also be of interest to the multi-disciplinary community of scholars studying the science-policy interface, as well as to those who have a particular interest in the debate on the risks and regulation of genetically modified crops.

The work presented in this dissertation was funded by a Ph.D. grant awarded by the Technical University of Denmark (DTU). The study was conducted at the Institute for Environment & Resources DTU, from September 2001 until September 2005. The work was initiated under the supervision of professor Poul Harremoës, and pursued under the supervision of associate professor Anders Baun. The dissertation is primarily based on five journal articles:

(i) Walker, WE, P Harremoës, J Rotmans, JP van der Sluijs, MBA van Asselt, P Janssen, **MP Krayer von Krauss**. (2003): Defining uncertainty. A conceptual basis for uncertainty management in model-based decision support. Integrated Assessment, 4, (1), 5-17.

(ii) **Krayer von Krauss MP**, E Casman, MJ Small. (2004). Elicitation of expert judgments of uncertainty in the risk assessment of herbicide tolerant oilseed crops, *Journal of Risk Analysis*, 24, (6), 1515-1527.

(iii) **Krayer von Krauss, MP**, MBA Van Asselt, M Henze, J Ravetz and MB Beck. (2005). Uncertainty and Precaution in Environmental Management. *Water Science & Technology*, 52, (6), 1-9.

(iv) **Krayer von Krauss, MP**, PHM Janssen (2005). Using the W&H integrated uncertainty analysis framework with non-initiated experts. *Water Science & Technology*, 52, (6), 145-152.

(v) **Krayer von Krauss, MP**, M Kaiser, V Almaas, J van der Sluijs, P Kloprogge (in preparation). Diagnosing & Communicating Scientific Uncertainty: a Case Study of Transgene Silencing.

All of the articles mentioned above are included as appendices to the dissertation. The papers are not included in this www-version but can be obtained from the Library at the Institute of Environment & Resources, Bygningstorvet, Building 115, Technical University of Denmark, DK-2800 Kgs. Lyngby (library@er.dtu.dk).

In addition to these, the following articles and abstracts have been published partially on the basis of this dissertation.

Harremoës, P, **MP Krayer von Krauss**. (2002). Caring, daring and precaution. Abstract No. 307. In: Achieving global environmental quality: Integrating science and management. SETAC 23rd Annual Meeting in North America, 16-20 November Salt Lake City, Utah. Abstract Book, p. 69. Society of Environmental Toxicology and Chemistry, Brussels.

Jensen, KK, C Gamborg, KH Madsen, RB Jørgensen, **MP Krayer von Krauss**, AP Folker, P Sandøe. (2003). Making the EU "risk window" transparent: The normative foundations of the environmental risk assessment of GMOs. *Environmental Biosafety Research*, **3**, 161-171.

Meyer, G, AP Folker, RB Jørgensen, **MP Krayer von Krauss**, P Sandøe, G. Tveit. (2005). *The factualization of uncertainty: Risk, politics, and genetically modified crops – a case of rape.* Agriculture and Human Values, **22**, (2), 235 – 242.

Gee, D., **MP Krayer von Krauss**. (2005). Late lessons from early warnings: towards precaution and realism in research and policy. *Water Science & Technology*, 52 (6), 25-34.

Krayer von Krauss, MP, WE Walker, JP van der Sluijs, PHM Janssen, MBA van Asselt, J Rotmans. (2006). Response to “To what extent, and how, might uncertainty be defined” by Norton, Brown, and Mysiak. *Integrated Assessment*, **6** (1), 89-94.

I would like to acknowledge Poul Harremoës for providing the vision and leadership which lead to me receiving a PhD scholarship to work on a topic that lay clearly outside of the departmental research priorities. For this and the other opportunities he provided me with, I am grateful. I would also like to thank Anders Baun for accepting to inherit the supervision of a project which few people in the department were familiar with, and for his unwavering support ever since then.

I would like to thank all of my co-authors for providing the intellectual sparring so valuable to my work, as well as the support required to cope with the loss of Poul Harremoës. In particular, I would like to acknowledge Marjolein van Asselt and Jeroen van der Sluijs for their support. I would also like to thank David Gee for the legwork that lead to the financial support provided for the conference Uncertainty and Precaution in Environmental Management by the European Environmental Agency.

At the Institute for Environment & Resources DTU, I would like to thank the librarians Grete Hansen and Helle Offenberg for their patience with me; Marianna Harder Olesen, Bo Skjold Larsen and Anne Harsting for helping me circumvent the administrative hurtles put up by "the system", and Mogens Henze for providing the financial support required to bring the work Poul Harremoës and I had initiated to a proper closure.

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Copenhagen, November 2005 Martin Krayer von Krauss

Abstract

In addition to possessing the expert knowledge and technical know-how required to provide public services, engineers and scientists function as an important source of legitimization for regulatory decisions. According to the liberal philosophy upon which the regulatory process is based, regulatory authorities should only intervene in instances where development could lead to harmful effects. Their decision to intervene should be based on facts, ideally considered within the framework of a rigorous rational methodology (e.g. risk assessment) so as to ensure that their interpretation of the facts is as objective as possible. This can be quite problematic in situations where scientific knowledge is limited, facts are uncertain, the stakes are high and values are conflicting.

In many cases, the complexity of the regulatory issues scientists and engineers are asked to study far surpasses that of typical laboratory problems. Knowledge is often limited and the facts are uncertain. That which has commonly been referred to under the umbrella term 'uncertainty' actually hides important technical distinctions. The well-established notion of uncertainty as a statistical or probabilistic concept leaves out many important aspects of the uncertainty encountered when assessing complex policy problems, such as the uncertainty generated by assumptions and ignorance of cause-effect relationships.

The precautionary paradigm[1] has emerged in the context of the above realisations. Under this paradigm, the role of scientists and engineers is to participate in the collective effort of producing, evaluating and applying knowledge, considering the interests at stake, and making a necessarily provisional decision. Formal methods are required for experts to assess uncertainty, and these methods must transcend the notion of uncertainty as a statistical or probabilistic concept. Ultimately, they should help foster a reflexive and humble attitude towards development.

This dissertation illustrates how a novel conceptual framework for uncertainty analysis, the Walker & Harremoës (W&H) framework, can be applied. The W&H integrated uncertainty analysis framework synthesizes a variety of scholarly contributions on uncertainty, in order to provide an interdisciplinary theoretical framework for systematic uncertainty analysis. Uncertainty is broadly defined as being *any deviation from the unachievable ideal of completely deterministic knowledge of the relevant system*. The framework distinguishes between three fundamental dimensions of uncertainty: the *location*, *level* and *nature* of uncertainty.

The W&H framework was applied to analyse two case studies related to the risk assessment of genetically modified crops: i) the risk of developing "super weeds" through the use of herbicide tolerant rapeseed; and ii) the phenomena of transgene silencing. As the experts involved were not familiar with the W&H framework, expert elicitations were used to communicate the W&H framework to the experts in such a way that their knowledge of uncertainty was obtained, without them being overly intimidated or confused by the novelty of the concepts they were presented with.

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[1] Throughout this dissertation, the terms "precautionary paradigm" are used to designate an approach and way of thinking, rather than a specific legal practice related to the Precautionary Principle.

The results obtained indicate that, not withstanding efforts to clarify the relationships between the concepts put forth in the W&H framework, experts did not use these concepts consistently. Nonetheless, the approach was successful in making explicit levels of uncertainty deeper than the statistical uncertainty commonly reported. As is the case for the concept of “risk”, different people will have different (subjective) perspectives on the concept of “uncertainty”. The approach successfully revealed that there are a variety of perspectives on the uncertainty that characterizes the cases studied. Thus, although the results yielded by studies such as the ones presented here may seem ambiguous, they are a valuable contribution to the discussion of the quality of the information underlying regulatory decisions.

Usikkerhed i videnskab med politisk relevans - Resumé

Ingeniører og videnskaber fungerer – ud over som leverandører af den fornødne ekspert viden og tekniske know-how til offentlige organer – som en vigtig kilde til legitimering af lovindgreb. Ifølge den gældende liberale filosofi bør de lovgivende autoriteter kun gribe ind i tilfælde, hvor udviklingen kan have skadelige konsekvenser. Deres beslutninger bør hvile på fakta, der ideelt set vurderes inden for rammen af en ren rationel metode – som fx risikovurdering – så man herigennem sikrer, at tolkningen af de foreliggende data bliver så objektiv som muligt. Dette kan være problematisk i situationer, hvor den videnskabelige viden er begrænset, de tilgængelige data usikre, indsatsen høj og de involverede værdier er i konflikt.

I mange tilfælde er de lov relaterede emner, som forskere og ingeniører bliver bedt om at behandle, langt mere komplekse end dem, der typisk optræder i laboratoriet. Den eksisterende viden er ofte begrænset, og dataene usikre. Den populære fællesbetegnelse 'usikkerhed' dækker reelt over vigtige tekniske skel. Det veletablerede usikkerhedsbegreb udelader – når det benyttes kun som et statistisk eller sandsynlighedsberegnende begreb – vigtige aspekter af den usikkerhed, man møder i behandlingen af komplekse lovmæssige problemer: fx den usikkerhed, der opstår som et resultat af formodninger og af ignorering af årsag - virkningsforhold.

Det her benyttede forsigtighedsparadigme er opstået som en konsekvens af de ovenstående erkendelser. I paradigmet er forskeres og ingeniørers rolle at deltage i den kollektive indsats for at producere, evaluere og anvende viden, vurdere de berørte interesser og træffe en beslutning, der i sin natur må være bundet af sin kontekst. Formelle metoder er nødvendige for at beskrive usikkerhed, og disse metoder må bevæge sig ud over definitionen af usikkerhed som et statistisk eller sandsynlighedsberegnende begreb. I sidste ende skulle de gerne afføde en refleksiv og ydmyg tilgang til udvikling.

Denne afhandling illustrerer, hvordan et nyt begrebsapparat for usikkerhedsanalyse, the Walker & Harremoës (W&H) framework, kan anvendes. Dette begrebsapparat sammenfatter et udvalg af videnskabelige behandlinger af usikkerhed for herigennem at skabe et tværfagligt, teoretisk metoderedskab for systematisk usikkerhedsanalyse. Usikkerhed defineres breds som *enhver afvigelse fra det uopnåelige ideal for totalt determinérbar viden omkring det pågældende system*. W & H-begrebsapparatet skelner mellem tre grundlæggende dimensioner af usikkerhed: usikkerhedens *lokalitet*, *niveau* og *art*.

W&H-begrebsapparatet blev anvendt til at analysere to feltarbejder med relation til risikovurderingen af genetisk modificerede afgrøder: i) risikoen for at udvikle 'super-ukrudt' gennem brugen af sprøjtegift tolerante rapsfrø og ii) risikoen for 'transgenic silencing'. Eftersom de involverede eksperter ikke var bekendt med W&H-begrebsapparatet, blev interview benyttet til at kommunikere begrebsapparatet til eksperterne på en måde, så deres viden om usikkerhed blev bevaret uden unødig irritation eller forvirring i forhold til nyheden af begreber, de blev præsenteret for.

De opnåede resultater indikerer – undtaget indsatsen for at klarlægge forholdet mellem de fremsatte begreber i W&H-apparatet – at eksperterne ikke benyttede disse begreber konsekvent. Ikke desto mindre resulterede deres tilgang i en fordybelse og forankring af eksplicitte usikkerhedsniveauer i forhold til den traditionelle statistiske usikkerhed. Ligesom det gælder begrebet 'risiko', vil forskellige mennesker have forskellige (subjektive) definitioner af begrebet 'usikkerhed'. Forskernes tilgang afslørede, at der eksisterer et udvalg af perspektiver på den usikkerhed, som karakteriserer de behandlede emner. Selv om resultaterne af forsøg som dem, der her er blevet foretaget, kan virke tvetydige, udgør de således et værdifuldt bidrag til diskussionen om kvaliteten af den information, der udgør grundlaget for regulative beslutninger.

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1 The case for conducting in-depth uncertainty analysis in policy relevant science

1.1 *Introduction*

Over the past 150 years, technology has had a profound impact on society. The internet, computers and cellular phones are just a few recent examples of the wide variety of technological innovations produced by natural scientists and engineers that have dramatically changed the day-to-day lifestyle of people in industrialised countries. However, the development of technology is not the only function of scientists and engineers in modern society. Unfortunately, technological development has been accompanied by a number of unexpected, adverse impacts on human health and on the environment. Because of their knowledge and skills, natural scientists and engineers are intimately involved in the regulatory process put in place by society to manage technological development and minimize its adverse side-effects.

This chapter argues that, given their role in the regulatory decision making process and the complexity of the problems they are often called upon to study, it is incumbent upon scientists and engineers involved in policy relevant science to communicate the uncertainty characterizing their assessments. Information about uncertainty contributes to the basis for deliberation on the precautionary measures warranted and the general desirability of technological innovations. It is also useful in informing adaptive decision making. Ultimately, uncertainty assessment should contribute to increasing reflexivity in the decision making process.

1.2 *Scientists and engineers as policy advisers*

1.2.1 A brief historical perspective

The origin of modern western thought can be traced back to what is known as the Enlightenment, a European intellectual movement of the 17th and 18th centuries. One of the major changes brought about by the Enlightenment was the displacement of the Church by science as the authoritative source of knowledge about man and nature.

The ideas of the early scientists Copernicus (1473-1543), Descartes (1596-1650) and Newton (1642-1727) were particularly instrumental in precipitating this change. Copernicus argued that the Earth revolved around the Sun, which at the time was a shocking theory because it contradicted the view that was presented in the Bible, according to which the Earth is at the center of creation and the Sun hangs from a celestial ceiling. If Copernicus was right, then the Bible could no longer be taken as a reliable source of knowledge. Scientific beliefs about the world would then need to be gathered in a radically new way. Descartes was instrumental in establishing how this should be done, calling for a methodological examination of knowledge before the "forum of Reason". Descartes believed that all material bodies, including the human body, are machines that operate by mechanical principles. Through Reason, man could understand these principles and use this understanding to improve his own condition. The new "scientific method" formulated by Descartes established procedures through which Reason could be applied to acquire knowledge that was free from arbitrary and unfounded or superstitious assumptions. Following this, the success of Newton in describing the laws that govern the motions of the planets in simple mathematical equations (his three laws of motion and his principle of universal gravitation) greatly bolstered man's confidence in his capacity to attain knowledge. Thus, by the end of the 18th century, science had replaced the Church as the chief source of man's understanding of the universe.

Between 1750 and the early 1900s, the technological innovations of the Industrial Revolution made it possible to greatly increase the transformation of natural resources and the mass production of manufactured goods. These innovations included the use of new raw materials (e.g. iron and steel), the use of new energy sources (e.g. coal, steam, petroleum and electricity), the advent of the factory system, and important developments in transportation and communication (e.g. steam locomotive, automobile, telegraph and radio).

The Industrial Revolution was accompanied by broad social changes such as the growth of cities and the explosion of urban populations. The problem of drinking water treatment received widespread public attention following the discovery that the London cholera epidemic of 1854 was due to a contaminated public well. Cholera epidemics forced most of Europe's cities to develop the means of providing clean drinking water and sanitation services to their populations. It was soon recognized that in order to deal with the many changes taking place in society, public officials possessing specialized technical knowledge were required. Thus, natural scientists and engineers became involved in the management of technological development. Before long, governments at all levels relied on scientists and engineers to occupy important positions within the civil service.

Two themes emerge from the brief historical account above. The first is that following the Enlightenment, scientists and engineers came to be regarded as the authoritative source of knowledge in society. When religion came to be perceived as being based on beliefs and superstitions, science came to be perceived as being unbiased and factual, the unique bearer of the True and therefore the Good. The second central theme is that scientists and engineers have become firmly anchored in the fabric of society. Through their research activities and their activities in the civil service, scientists and engineers function as both the source of technological innovation, and as key participants in the management of this technological innovation.

1.2.2 The involvement of science in the policy process

The broadening scope of technological applications, coupled with increasing public concern over the impacts of these technologies, led to the establishment of the modern regulatory agencies we know today (e.g. Environmental Protection Agencies). Because of their knowledge and skills, a myriad of different scientists and engineers are involved in the regulatory process. Some scientists and engineers are employed within the agencies themselves and perform the specialized tasks associated with the activities of the agency. Others are employed outside the agency (e.g. in industry, consulting or academia), but act as advisers to the agency in situations where important regulatory decisions must be made concerning issues where scientific expertise is required.

The function of these scientists and engineers is to provide decision makers with scientific assessments upon which to base their decisions. An important goal of the regulatory process is to ensure that the health of the public and the environment are protected from the potential side-effects of technology. Thus, in many cases, the subject of scientific assessments is a matter of public interest, such as minimising the risks posed by chemicals to human health and the environment. Examples of frequently encountered assessment methods are risk assessment and cost-benefit analysis.

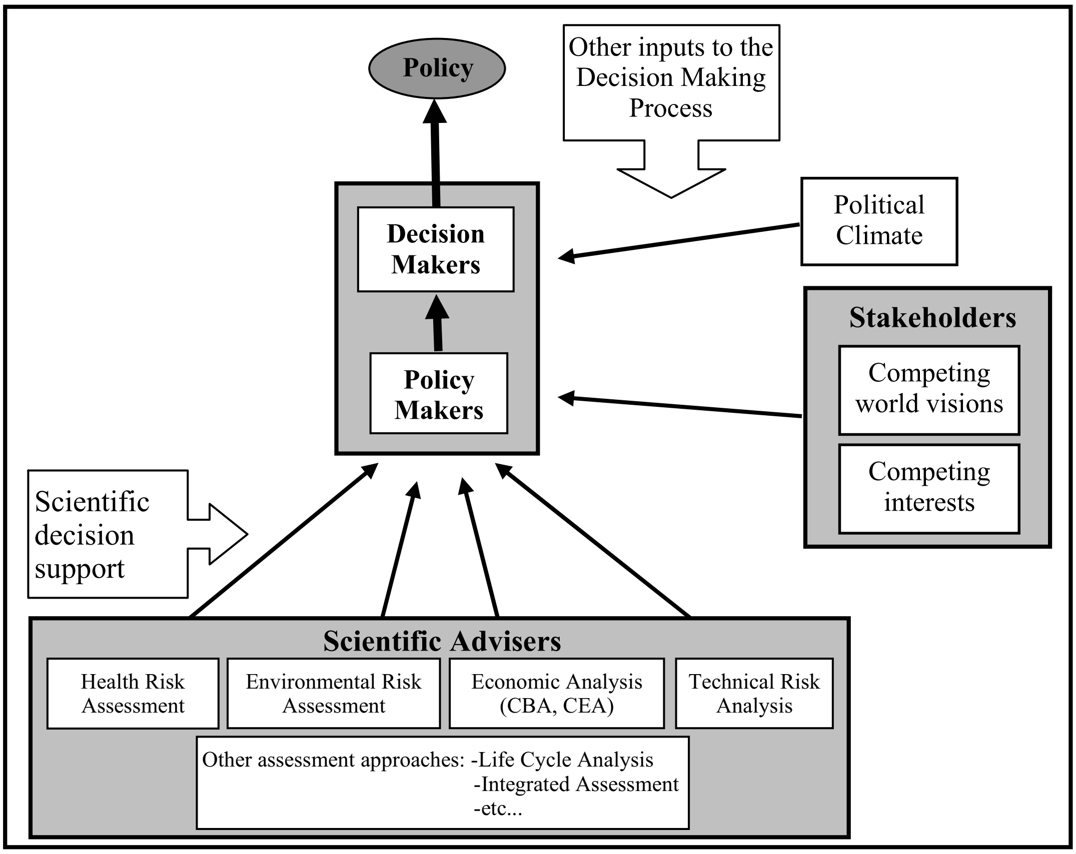

Figure. 1.1 Model of the regulatory process (adapted from OXERA, 2000).

The function of scientific advisers is illustrated in Figure 1.1. The Figure presents an idealized model of the decision making process (OXERA, 2000). The model distinguishes four different roles in the decision making process: the decision maker, the policy maker, the scientific adviser and the stakeholder representative. Their respective functions can be described as follows:

- **Decision maker** – a person with the authority to take a policy decision. This may be a government Minister, or a person or body with the delegated authority to take a decision in the name of a Minister.
- **Policy maker** – a person or organization charged with assisting a decision taker in reaching a decision by providing policy analysis or generating policy options.
- **Scientific advisor** – a person or organization responsible for providing scientific input to policy-making or decision making, whether from within or outside the civil service. This includes both scientists expert in narrow disciplines relevant to the problem in question, and broader-based scientists

able to integrate several disciplines.

- **Stakeholder representative** – a person or organization representing the interests and opinions of a group with an interest in the outcome of a particular policy decision.

The term *"decision support* " is used to describe the type of scientific activity conducted by Scientific Advisers. Throughout this dissertation, this type of activity is at times designated as policy relevant science, decision support sciences, or regulatory sciences. Decision support sciences can be thought of as *structured search processes that aim to provide knowledge that facilitates decision/ policy making* (van Asselt, 2000). A number of different assessment approaches can be characterized as decision support, amongst which some commonly employed methods are environmental impact assessment, life-cycle analysis, ecological and health risk assessment, technical risk analysis, cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA).

1.2.3 The liberal foundation of the regulatory system

Although the management of technological developments requires the expert knowledge and technical know-how possessed by scientists and engineers, the necessity of involving scientists and engineers in the regulatory process is more profound than this pragmatic requirement may suggest. To understand the role of science in the modern regulatory process, it is useful to consider some of the basic principles upon which it is based.

One of the founding principles of the modern regulatory process is the liberal principle of *state neutrality*. According to traditional liberalism, the state should be neutral with regards to particular attitudes and values, that is, conceptions of the good. Such conceptions are seen as private rather than public matters, and the law is supposed not to favour any particular conception. On the contrary, values are deemed to be illegitimate as justification for political action. Rather than being based on values, decisions should stem from a rational consideration of the facts. Thus, science is invested in the regulatory process in order to provide an impartial source of facts upon which policy decisions can be based.

A second founding principle of the regulatory system, the *harm principle*, was formulated more than a hundred years ago by John Stuart Mill. It basically states that persons should be free to do whatever they like, unless their activities are harmful to others. The principle was originally intended to protect individual freedom in matters of, for instance, religion and sexuality. Today, the principle is applied to many areas of regulation, including regulations on the application of new technologies.

The influence of the principle of state neutrality and the harm principle is to create a requirement for facts about harm. Harm is the trigger for regulatory intervention, and only facts can determine the existence of this harm. In practice, this means that in order to justify regulatory intervention, "threats" should be defined in as specific terms as possible and ideally in quantitative form. The basis for action should be a factual one, ideally developed through the use of a rigorous rational methodology (e.g. risk assessment) to ensure that the interpretation of the facts is the most objective possible (Fisher, 2005).

As a result of this, when a party disagrees with a particular technological enterprise, the most legitimate grounds for disagreement is to prove (or claim) the harmfulness of the enterprise in question. In other words, to be effective, opposition must be expressed in terms of risk, the existence of which is to be demonstrated using science (Jensen *et al.*, 2003; Meyer *et al.*, 2005). As will be explained further on, this can be quite problematic in situations where scientific knowledge is limited, facts are uncertain, stakes are high and values are conflicting.

1.3 Complexity

An important distinction between decision support sciences and conventional sciences lies in the complexity of the problems studied. Conventional sciences tend to focus on isolated systems under controlled circumstances. Decision support sciences must often deal with real world problems, the complexity of which far exceeds the complexity of the problems typically studied in conventional sciences. This realisation has lead to the designation of a new class of problems, *complex problems*, which includes issues such as global climate change, chemical pollution and stratospheric ozone depletion. Complex problems are characterized by one or more of the following properties (adapted from NRC, 1988; van Asselt, 2000; Funtowicz *et al.*, 1999; Holling, 2001; UNESCO, 2005):

- There is not one problem, but a tangled web of related problems;
- The underlying processes interact with one another within some sort of hierarchy;
- The dynamics of the systems studied are not necessarily regular, but are characterized by synergistic and/or antagonistic relationships, indirect relationships, long delay periods between cause and effect, thresholds or non-linear behaviours;
- The issue lies across or at the intersection of many disciplines, i.e., it has economic, environmental, socio-cultural and political dimensions;
- There are a number of different, equally legitimate and plausible, perspectives on how the problem should be conceived.

The hierarchical relationships encountered in complex systems may be hierarchies of inclusion and scale, as in a watershed that includes streams, ponds, rivers, lakes and the sea, at ascending levels. Alternatively, they may be hierarchies of function, as in an organism that is comprised of a number of separate organs, each performing a function subordinate to the overall function of the organism, which itself may be sub-ordinate to the overall function of an ecosystem. Environmental systems may also include human and institutional sub-systems, which are themselves systems.

In complex systems, causes and effects are not always obviously related. Pushing on a complex system "here" often has effects "over there" because the parts are indirectly dependent of one another. Similarly, the future conditions in a complex system may not always follow closely on the conditions in the past. When a particular threshold is exceeded, the system can abruptly shift away from a period of relative stability in one state, to another, fundamentally different state. An example is that of the impacts of climate change on thermohalyne circulation, the large-scale ocean circulation that currently transports heat from the mid-latitudes to the high latitudes. Geological analysis and model experiments suggest that these currents can be on or off, and that the two states are characterized by drastically different environmental conditions in Western Europe (Broeker, 1997; Cusbasch *et al.*, 2001). Similar dramatic regime shifts have now been documented for a wide range of environmental systems (Scheffer *et al.*, 2001; Scheffer & Carpenter, 2003).

Because of the hierarchical, indirect, synergistic and non-linear relationships that can characterize complex systems, any attempts at reductionist analysis will be inherently incomplete. The concepts used to represent the functionings of the system will necessarily be rough approximations. The empirical data required may not be available, or may only be available in a form that requires interpreting or massaging to make it relevant to the problem at hand. Thus, in addition to the obvious uncertainties resulting from the operations of data collection and aggregation, the analysis will be characterized by deeper, structural uncertainties, not amenable to quantitative analysis. Similarly, every analyst of a complex system will operate at a certain level in the hierarchy of the system, with certain observational and analytical tools, and with certain prior experiences. The result of their separate observations and analyses are not at all arbitrary; but none of them can singly encompass the whole system. There is no unique, more plausible or more legitimate approach through which to analyse the system. The choice of which analysis approach to use is therefore value-laden. The values involved are those embodied in the societal or institutional system in which the science is being done.

An approach inherent to conventional sciences is that of reductionism, whereby an overall system is understood as an assembly of sub-systems. By studying and understanding each of the sub-systems, an understanding of the overall system is achieved. While the reductionist approach has led to many great achievements in Western science, the properties of complex problems, explained in more detail below, greatly reduce the effectiveness of the approach. Systems that are complex are not merely complicated; by their nature they involve deep uncertainties and a plurality of legitimate perspectives. Thus, rational, reductionist approaches to analyzing risks, such as risk assessment and cost-benefit analysis, will have only limited value.

Funtowicz *et al.* (1999) have illustrated the challenges related to the analysis of complex systems using the Hindu parable of the six blind men touching an elephant. One blind man touched the side of the elephant and said it was a wall. Another blind man touched the ear and said it was a large leaf of a tree. Yet another blind man was holding a leg and thought it was a tree trunk. Still another blind man took hold of the elephant's trunk and said it was a snake. Someone else was touching the elephant's tusk and believed it was a spear. Another blind man had the elephant's tail in his hand and was calling it a rope. All of the blind men were touching the same reality but were understanding it differently. Each conceived the object on the basis of his own partial imagination process, but none of them could visualise the whole elephant. Only an outsider possessing the sense of sight was able to visualise the whole elephant. Similarly, in science, a number of different experts, each from a different discipline, may produce a number of different analysis of a complex system. While each of these analyses may be a correct partial description, they fall short of a holistic grasp of the system. Although a truly holistic grasp will always remain unachievable, policy relevant science must strive to integrate partial views into a richer view of the whole.

1.4 Policy relevant science

Since the 1960's, the social dimensions of science have increasingly become a subject of study by philosophers, sociologists and historians of science. One of the central themes that have emerged from these studies has been a strong critic of the view of science as the provider of the objective truth. Following the publication of the seminal work by Thomas Kuhn (*The Structure of Scientific Revolutions,* 1962), it became increasingly apparent that rather than being the result of value-neutral, dispassionate observations, scientific knowledge is constructed and negotiated according to a social process. That which is considered acceptable or unacceptable as knowledge is largely determined by negotiations within the scientific community (Kuhn, 1962; Knorr-Cetina & Mulkay, 1983; Latour & Woolgar, 1986). These negotiations are influenced by social factors such as rhetoric, politics, and personal reputations. Because of this, scientific conclusions, or the `truth´ perceived, will depend on the actors and circumstances involved, and are therefore not definitive accounts of the physical world. Rather, they are social constructions which may evolve as circumstances change.

Funtowicz and Ravetz (1990) were amongst the first scholars to interpret the constructivist paradigm described above in terms of policy relevant science. They introduced the term "*post-normal science*" to designate science conducted in contexts of high political pressure, large decision stakes, disputed values and pervasive uncertainty. The scientific nature of decision support activities derives from the fact that they are conducted in a structured, methodological way. However, while the results of conventional science most often serve to increase understanding of the natural universe or to contribute to technological advancement, the results of decision support are used to facilitate decision making in the policy process. In this context, the leading scientific problems are no longer derived from abstracted scientific curiosity or industrial imperatives. Rather, the research agenda for decision support sciences is set in the context of complex policy problems. Typically in such contexts, political and ethical considerations influence how the problem is defined, which research questions are to be given priority, and often which research groups should be mandated to investigate the problem. Thus, Funtowicz and Ravetz (1990), Wynne (1992) and others (e.g. see Krimsky & Golding, 1992; Jasanoff & Wynne, 1998) argue that decision support sciences are particularly prone to the "subjective pitfalls" highlighted by social constructivism. Rather than "hard" facts and "soft" values, decision support sciences should be considered "soft" sciences providing the basis for "hard" decisions.

Funtowicz (2004) proposed that there are (at least) two different visions of the relation between science and decision making in policy processes, which he labels as "modern" and "precautionary".

1.4.1 The modern vision of the science-policy interface

To a large extent, the vision of science that emerged following the Enlightenment, which is of science as a special and higher form of knowledge, the provider of objective facts about the natural world, still underlies the modern paradigm for science conducted at the science-policy interface.

In the modern paradigm, policy should follow from the consideration of objective scientific facts. This vision is “reductionist”, in that it understands the world in terms of component parts that allow for abstracting the part from the whole, as well as increasingly specialized knowledge of each component part The result of this “logic of component thinking” is a view of the world which is referred to as “technocratic”, according to which the world is perceived as a system that can be technically redesigned in ways that make it more efficient and controllable. Typically, technocrats tend to see technical solutions as applicable to most social and cultural situations (Fischer, 2000). Problem solving, in short, is reduced to a technical matter of plugging solutions into different social contexts. In addition to being reductionist and technocratic, the modern paradigm can also be characterized as “positivistic”, in that it accepts a separation of facts and values (Proctor, 1991), claiming that empirical research can and should be conducted without normative (value-dependant) references, and viewing uncertainty as a temporary and resolvable certainty deficit. In the modern paradigm, the role of science is to speak truth to power (Wildavsky, 1979).

1.4.2 The precautionary vision of the science-policy interface

The precautionary paradigm holds that through complex issues such as water management, climate change and endocrine disruptors, it has become apparent that in many cases, complete knowledge or ‘truth’ is not achievable. In such cases, there are relatively few simple 'facts' upon which decisions can be based. While numerical models are often used to investigate complex systems, the properties of such systems, the intricacies of modeling and the lack of transparency in complicated models imply that assessments involve value-laden problem definitions and assumptions. Assessments of policy problems involve uncertainties of many sorts, including irreducible lack of knowledge and ignorance. Within the precautionary paradigm, scientific knowledge is perceived as socially constructed to some extent, in that it necessarily offers an account of the physical world that is mediated through social processes; and that it therefore cannot be considered definitive. Scientific conclusions are claims that have been deemed to be adequate by a specific group of actors in a particular cultural and social context. Scientific assessments may facilitate decision making, but their conclusions cannot be defended with reference to objectivity and neutrality. Problem framing and the identification of relevant scientific disciplines and knowledge resources are political decisions. In the precautionary paradigm, uncertainty is a phenomenon inherent to science, which should be recognized and taken into consideration in the decision making process.

As will be seen below, the precautionary paradigm has been crystallised in more definite terms within the debate surrounding the Precautionary Principle.

1.5 The Precautionary Principle

To a significant degree, the environmental “surprises” witnessed in the past 50 years have been due to disregarded knowledge, uncertainty or ignorance (Harremoës *et al.*, 2001). Too frequently, the growing innovative powers of science seem to outstrip its ability to predict the consequences of its applications. At the same time, the scale of human interventions in nature increases the chances that hazardous impacts may be both serious and global. Therefore, the Precautionary Principle has been proposed to guide decision making in situations of high uncertainty and potentially large-scale, irreversible impacts.

A central conclusion of the European Environmental Agency report on the Precautionary Principle (Harremoës *et al.*, 2001) concerns the importance of recognizing and fully understanding the nature and limitations of scientific knowledge. No matter how sophisticated knowledge is, it will always be subject to some degree of uncertainty and ignorance. By their nature, complex problems have traditionally been inadequately addressed in the decision making process, and that which is commonly referred to under the umbrella term 'uncertainty' actually hides important technical distinctions. Engineers and scientists are taught at an early stage how common problems such as sampling errors and imprecise measurements generate uncertainty in experimental results, and how this uncertainty can be dealt with using statistical methods. However, this well-established approach to uncertainty analysis leaves out many important aspects of the uncertainty encountered when assessing complex policy problems (ESTO, 2001).

The regulatory process can at times be the stage of bitter disputes amongst stakeholders, all of whom are trying to steer the process in a direction that best serves their particular interests. Proponents of potentially harmful activities often tend to use uncertainty as an argument for postponing or waiving regulation (Michaels & Monforton, forthcoming; Michaels, 2005). They demand certain knowledge about the harm caused, as well as about the cause-effect relationship leading to the harm, to justify the need for regulation. Such a strategic behaviour towards uncertainty is not only observed among the defenders of business interests, but also among NGO's and other interest groups (Jasanoff, 1994; Fischer, 2000). While striving to ensure transparency and consistency in decision making, regulators themselves often become trapped in a quest for certainty (van Asselt and Vos, 2005). Experience demonstrates that often, conclusive evidence of harm only becomes available once harm has been done (Harremoës *et al.*, 2001). In many cases, the politicisation of uncertainty (i.e., emphasizing or amplifying uncertainty to serve a specific interest) paralyses the environmental management process (Funtowicz & Ravetz, 1990; Michaels, 2005), a particularly undesirable outcome when the consequences of regulatory inaction could lead to irreversible harm.

There is no universally accepted definition of the Precautionary Principle. Gee and Krayer von Krauss (2005) present one formulation of the principle stating that it

> "*provides justification for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction*".

This formulation does not clarify who has the burden of proving absence or presence of threats of harm, nor how or who is to determine the appropriateness of the level of scientific evidence. Another reading of the precautionary principle (Rogers, 2003) holds that

> "*the proponent of an activity posing uncertain risk bears the burden of proving that the activity poses "no" or an "acceptable" risk before the activity can go forward*".

1.6 The precautionary paradigm revisited

Two themes emerge from the above statements of the Precautionary Principle: one concerns the generation (and presentation) of policy relevant scientific knowledge including its uncertainty, while the other concerns the application of (uncertain and perhaps even partisan) scientific knowledge in political, regulatory and judicial decision making processes (Krayer von Krauss *et al.*, 2005). In view of further articulating the precautionary paradigm, it is useful to consider the insights generated within three bodies of literature: i) the literature on deliberative decision making, ii) the literature on adaptive management, and iii) the literature on reflexivity.

1.6.1 Deliberative decision making

One of the profound implications of the Precautionary paradigm is its bearing on the legitimacy of regulatory decisions. In a system where regulators are meant to be the value-neutral administrators who base all of their decisions on facts, what may justify regulatory interventions and what kinds of interventions are justifiable, in situations where the facts are uncertain? The problem is that this is the case with nearly all environmental and public health issues, which leads to a situation where regulators cannot act, and/or a façade of objectivity is constructed to justify action. The challenge is thus to conceive the regulatory process in a way that ensures the ability of regulators to act in an open and accountable manner in situations of uncertainty. In response to this challenge, many scholars argue for a regulatory decision making process where deliberation amongst actors plays a central role (Funtowicz & Ravetz, 1990; NRC, 1996; RCEP, 1998; Fischer, 2000; ESTO, 2001; Wynne, 2001; Klinke & Renn, 2002; Harremoës *et al.*, 2001, Fisher, 2005).

Deliberative decision making aims to achieve a synthesis of scientific expertise and public values on a specific issue. Here, the notion of the "threat" that justifies regulatory intervention is interpreted broadly, such that there is no pre-defined or precise definition of the acceptability nor the nature of the risk (Fisher, 2005). The legitimacy of regulatory decisions is restored through an increased democratisation of decision making, whereby a variety of actors, representing as wide a spectrum of perspectives as possible, are invited to participate in the decision making process. Here, conflicts are resolved in consultation rather than in confrontation (Webler, 1995; Jasanoff, 1994).

While deliberative decision making processes begin with the consideration of scientific inputs (i.e., risk assessments), this is only one activity in a more complex evaluation procedure. The scientific inputs are subsequently brought into a deliberative arena for debate in a wide forum which includes stakeholders and public interest groups in addition to scientists and decision makers. Funtowicz and Ravetz (1990) designate this process as *extended peer review*. The expectation is that the participants in the debate (i.e., the extended peers) will introduce additional factors to the decision making process. There are no methods or guidelines pre-determining which factors should serve as the basis for decision making, and these will vary from one context to another. The ambition is to create a synergistic process, whereby deliberation generates a body of considerations that is richer than that which would be generated if each of the stakeholders simply put forth their considerations individually, without reflecting on those of others. In other words, the relevant aspects of a decision will co-evolve as they are considered (Fisher, 2005).

It is not possible to provide general guidance as to what should form the basis of a deliberative decision. In nearly all circumstances, science will be an important consideration (Stirling, 2001), but other factors may also be relevant. Such factors may include *extended facts* (Funtowicz & Ravetz, 1992), i.e., information stakeholders and laypersons possess on the extent and nature of the risk. Examples of extended facts include anecdotes circulated verbally, edited collections of such materials prepared by citizens' groups and the media, the experiences of persons with a deep knowledge of a particular environment and its problems, or the materials discovered by investigative journalism.

While the training and employment of experts can socialise them to abstract, generalized conceptions, those whose livelihoods depend on the problem will have a keen awareness of how general principles are realised in their backyards. The traditional, intuitive and particularized knowledge the affected lay people possess gives them a firmer grounding in real world operational conditions. Often, too, their knowledge may be based on different perceptions about what is salient, or what degree of control is reasonable to expect or require, whereas the knowledge of technical specialists may simply be based on the common practice, without further reflection. Thus, in addition to contributing to the formulation of policy problems, local knowledge can also help determine which data, models and assumptions are relevant in particular cases.

One prominent example of a contribution from lay knowledge relevant to the regulatory process concerns workplace awareness of emerging patterns of ill health (Harremoës *et al.*, 2001). The histories of usage of asbestos (Gee & Greenberg, 2001) and PCBs (Koppe & Keys, 2001) provide examples where workers were aware of what regulators subsequently recognised to be a serious problem. Similarly, local communities may become aware of unusual concentrations of ill health before the authorities, as occurred in the Love Canal case (Gilbertson, 2001).

In addition to extended facts, lay people and stakeholders can raise a number of ethical considerations that are relevant to the decision making process. These may include different perspectives on the acceptability of risk in the face of uncertainty, issues of fairness and environmental justice, visions on future technological developments and societal change, and preferences about desirable lifestyles and community life. While the extended facts provided by stakeholders and lay people may broaden the factual basis for decision making, it is the process of including their additional perspectives and values that legitimizes the decisions made in the face of complexity and uncertainty.

An important reflection on deliberative approaches is that public preferences do not necessarily match the real interests of the public since the preferences are clouded by misinformation, biases, and limited experience (Klinke & Renn, 2002). Of course, the input provided by stakeholders and lay persons should be subjected to the same intensity of critical scrutiny as specialist expertise (Harremoës *et al.*, 2001). Just like expert knowledge, lay knowledge can be uncertain, partial, biased etc... Simply organizing a platform for mutual exchange of ideas, arguments, and concerns does not suffice to ensure fair and competent policies (Renn, 1999). Mixing all of these knowledge and value sources creates the danger that subjective perceptions supersede factual assessments, or that the rhetoric of powerful actors dominates the input of less powerful and organised actors, who may be those who must bear the risks. This has given rise to a growing number of formal methods to conduct deliberative decision making. Common to all of these methods is the aim to ensure that the contributions of different actors are embedded in a dialogue setting that guarantees mutual exchange of arguments and information, provides all participants with opportunities to insert and challenge claims, and creates an active understanding amongst all participants (Forester, 1999; Fischer, 2000). Examples of such methods and approaches include multi-criteria analysis (Jansson, 2001; Stirling & Mayer, 2001), constructive technology assessment (Rip *et al.*, 1996), technical options analysis (Ashford 1991; Tickner, 2000), consensus conferences and scenario workshops (Andersen & Jæger, 1999), cooperative discourse (Renn, 1999) and participatory policy analysis (Fischer, 2003).

1.6.2 Adaptive management

The basic idea of adaptive management - implementing policies as experiments – first emerged in the 1970s and 80s in the field of natural resource management (Holling 1978, Walters 1986). Adaptive management is grounded in the admission that humans do not know enough to manage ecosystems. Thus, adaptive management formulates management policies as experiments that probe the responses of (eco)systems as people's behaviour in them changes. Rather than thinking of ecosystem management as the task of managing nature, adaptive management aims to manage the *people* who interact with the ecosystem (Lee, 1999). In practice, it was proposed that this vision be enacted by developing computerised models, preferably using the best available interdisciplinary knowledge, by using these models to test the impact of different policy measures, and by identifying key uncertainties in the models. These uncertainties could then be explored by conducting focused, large-scale management experiments in the field which, through monitoring efforts, would directly reveal the impacts of the policies tested, at the space and time scales where future resource management would actually occur, and the experience gained could then be applied on a large scale (Walters, 1997).

Adaptive management implies a change in the way uncertainty is perceived. In adaptive management, science and knowledge are considered intrinsically uncertain, and it is accepted that regulatory decisions must therefore be made in a context of uncertainty (Walker *et al.*, 2001). Thus, information about uncertainty is used proactively, as a resource in the decision making process. The goal of the policy experiments is to learn something about the ecosystem's processes and structures, in view of designing better policies and experiments. Because ignorance of ecosystems is uneven, management policies should be chosen in light of the assumptions they aim to test, so that the most important uncertainties are tested rigorously and early (Lee, 1999).

Although adaptive management has been applied in many different contexts, to date, it has been much more influential as an idea than as a practice. Experience has shown that there are many human and institutional barriers that can hinder the proper implementation of adaptive management. For example, the complexity of the ecosystems and human behaviour implies that causal understanding is likely to emerge slowly (i.e., over several years). However, policy formulation is often driven by relatively short funding and election cycles, thereby making it difficult to treat long-term crises in the natural world effectively. In some cases, agency professionals may view admission of uncertainty as an admission of weakness (Gunderson *et al.*, 1995). It can be very difficult to convince people who adopt such views that they will gain more credibility by openly admitting uncertainty, and then suggesting proactive ways of dealing with that uncertainty.

1.6.3 Reflexivity

Reflexivity is a concept that has been central to social scientific thought since the 1990s, after the writings of authors such as Beck, Giddens and Lash on modernity, risk and the cultural dimensions of contemporary environmental issues (Beck, 1992; Giddens, 1991; Beck *et al.*, 1994; Lash *et al.*, 1996). Beck introduced the term "reflexive modernization" to designate a new stage of development which, according to him and others, society has entered. This new era is characterized by a change in the way society perceives its relation to the risks to which it is subjected. In the previous era, known as “modernity”, society was exposed to risks generated by external factors such as nature, which society responded to by developing technologies to overcome risks and increase welfare. In the current era of reflexive modernization, the principle risks to which society is exposed are no longer generated by nature, but by society itself: it is the unintended side-effects of technological development that currently pose the greatest threat to our welfare. Rather than producing ever-increasing security and welfare for people, industrial society has come to produce ever-greater risks for people and the environment.

The notion of reflexive modernization has led to calls for the development of institutions and approaches to decision making that foster reflexivity in the regulatory context (Hajer, 1995; Flyvbjerg, 2001). The extent to which a decision-making process can be considered reflexive hinges upon the ability of the policy community to recognize the limitations of the knowledge base underpinning a decision, draw upon the collective knowledge and experience of the past to design a policy, monitor and assess the effects of this policy, and adjust the policy accordingly. In this sense, reflexivity implies both “reflex” and “reflection” (Craye *et al.*, 2005). Reflex in reference to the response of society to the unintended consequences of technological development. Reflection in reference to the careful consideration of the limitations of the information available, the diversity of viewpoints, and the multiplicity of possible policy options.

The rationale here is that the best way to cope with the reflexivity of the modernization process is to increase the reflexivity of the decision making process. In other words, expect surprises, seek them out, and deal with them as they arise. Reflexive decision making will require the actors of the policy community to change their attitude towards uncertainty, conflict and decision making. A pro-active attitude which recognises and accounts for uncertainty is required, and conflict must be perceived as a learning opportunity rather than as a battle to be fought and won.

In a reflexive policy community, conflict is treated as an important catalyst to reflection. Conflict may lie in the discrepancy between one's vision of the ideal and one's perception of reality, or in the discrepancy between one's vision and the vision of other actors in the policy process. They may have a different vision of the ideal, a different perception of reality, a different perception of the problem that is preventing the realization of the ideal, or, a different perception of how this problem should be solved. As has been mentioned previously, a frequent source of conflict lies in the interpretation of uncertainty. The actors in the policy process must collectively determine the quality of the information at hand, and the level of protection justified. In the process, the sources of uncertainty identified will be an important subject of reflection.

A reflexive policy community is one that is committed to learning about how decisions may affect society and the environment. Advocates of deliberation argue that reflection is provoked through deliberation, as the different actors of the reflexive policy community seek to develop a shared understanding of the issue under investigation. The insight gained is then applied and implemented through a policy decision, the effects of which are monitored. Inquiry is a transaction with the situation in which knowing and doing are inseparable. In such an approach, the role of the expert is deeply transformed (Schön, 1982; Fischer, 2000; Forester; 1999). Rather than providing an optimal technical answer, the role of experts is to participate in the collective effort of producing, evaluating and applying knowledge, considering the interests at stake, and making a necessarily provisional decision.

1.7 Conclusion

Although many still perceive science as the provider of the objective truth, it is now increasingly being recognised that science is a social process of knowledge production, subject to its own social and cultural biases. As society becomes more aware of the complexity of the problems it faces and of the difficulties of studying these problems through the scientific approach, it can be expected that the precautionary paradigm will gain in influence, slowly displacing the modern paradigm. Under the precautionary paradigm, scientific conclusions are no longer considered definitive, and the legitimacy of regulatory decisions can no longer be defended solely by referring to scientific assessments. This legitimacy deficit is compensated through an increased democratisation of the decision making process. The precautionary paradigm also implies a shift towards a regulatory process that is more adaptive and reflexive. Adaptive in the sense that regulatory decisions are considered inherently uncertain, temporary and experimental, subject to revision as new information emerges. Reflexive in the sense that the actors in the policy process are perceived as members of a learning community that are capable of collective reflection, and collective responses to resolve conflicts between a vision of the ideal and the reality experienced.

The precautionary paradigm has profound implications for the role of experts in the decision-making process. Experts can no longer place messy factors such as the economic, social and political aspects of an issue beyond the boundaries of their narrowly defined technical field. Rather, they must accept these factors as part of their legitimate field of concern, opening up to complexity, instability, and uncertainty. Experts are now expected to reflect publicly on the quality of their knowledge, explicitly revealing their uncertainties and opening up to questioning and confrontation by other members of the policy community. They must emancipate themselves from the widespread statistical or probabilistic understanding of uncertainty, to recognize the full spectrum of the uncertainties characteristic of policy relevant science.

There is no reason to believe that it will be easy to shift from the modern to the precautionary paradigm. Professional cultures are not easily transformed, especially in the situations of high stakes and disputed values that characterize many regulatory decision-making processes. The competences required for scientists and engineers to function well in this new context will not be acquired simply as a result of deciding to do so. It is very likely that the shift, where it occurs, will proceed gradually and with difficulty as the different actors of the policy community increase their willingness to experiment with new modes of interaction and decision making. Institutional arrangements and new methodologies will help facilitate the transition required.

Methods for assessing uncertainty can help experts fulfill their role under the precautionary paradigm. Through the application of these methods, experts are brought to diagnose the uncertainty characterising their assessments, and explicitly communicate it to the other actors in the policy community. As will be explained in chapter 2 of this dissertation, there is a distinction to be made between the uncertainty characterizing information, and the quality of information. The results of uncertainty analysis contribute to a qualified discussion of the quality of the information underpinning a policy decision. The quality of the information available can then be considered in determining the extent of the precautionary measures that are warranted in a given situation, and how monitoring resources should be allocated.

This dissertation presents a novel method for diagnosing and communicating uncertainty in policy relevant sciences. The aim is to illustrate the application of a method that can help scientists and engineers involved in policy relevant sciences fulfill their new role under the precautionary paradigm. Chapter 2 of this dissertation will present the conceptual framework upon which the method is based, essentially examining the question: how does uncertainty manifest itself in the context of policy relevant science? Chapters 3 and 4 illustrate how this conceptual framework was applied through expert elicitations focusing on two different case studies related to the risk assessment of genetically modified crops. Chapter 5 offers reflections on the experiences gained in the process of applying the conceptual framework.

2 The anatomy of uncertainty in policy relevant sciences

2.1 Introduction

Because of the globalization of issues and the interrelationships among systems, the consequences of making wrong policy decisions have become more serious and global – potentially even catastrophic. Nevertheless, in spite of the profound and partially irreducible uncertainties and potentially serious consequences, policy decisions have to be made. Scientific decision support aims to provide assistance to policy makers in developing and choosing a course of action, given all of the uncertainties surrounding the choice.

Policy makers and the scientists and engineers involved in policy relevant sciences have little appreciation for the fact that there are many different dimensions of uncertainty, and there is a lack of understanding about their different characteristics, relative magnitudes, and available means of dealing with them. Even within the different fields of decision support (policy analysis, integrated assessment, environmental and human risk assessment, environmental impact assessment, engineering risk analysis, cost-benefit analysis, etc.), there is neither a commonly shared terminology nor agreement on a generic typology of uncertainties.

The aim of this chapter is to explain a novel conceptual framework for the systematic treatment of uncertainty in decision support, put forth by Walker, Harremoës and co-workers (Walker *et al.*, 2003) (hereafter referred to as the W&H framework[2]). Emphasis will be placed on categories of uncertainty that have traditionally been inadequately acknowledged by scientists and engineers, due to the statistical approach to uncertainty analysis prevailing in these fields. Prior to launching into the explanation of the W&H framework, it is useful to first examine the context in which it is intended to be applied.

2.2 Uncertainty and quality in policy relevant science

As uncertainty is a concept subordinate to quality, uncertainty assessment should be viewed as part of a greater process of quality control. The distinction between uncertainty and quality is often overlooked and it is often assumed that high quality is equivalent to low uncertainty. However, the relationship between quality and uncertainty is not so straightforward, and it is worth spending some time here on recalling the distinction between the two.

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[2] The framework was named by the author in recognition of the roles of Warren Walker as the principal author, and Poul Harremoës as an indispensable unifier within the group of authors. The framework is the result of a collective effort by all of the co-authors of the Walker *et al.* (2003) paper.

Quality can be defined as "the totality of characteristics of an object that bear on its ability to satisfy an established need"[3]. Whereas uncertainty is an attribute of knowledge, the quality of knowledge is an attribute of the relationship between knowledge and the purpose for which it is intended to be used. Thus, depending on the function for which it is intended, uncertain knowledge may still be considered of good quality.

To illustrate the distinction between uncertainty and quality, Funtowicz and Ravetz (1993) use the example of deforestation in the Himalayas. The estimates of the per capita fuelwood consumption vary by a factor of almost one hundred. Nonetheless, all serious studies agree that their numerical assessments imply that the problem exists and that its solution is urgent (Thompson and Warburton, 1985). In this case, although the estimates of per capita fuelwood consumption are subject to considerable uncertainty, they are of sufficient quality to determine a need for action. Similarly, climate change predictions provide an example of high certainty, low quality knowledge. Some climate simulations predict a rise in the average temperature of the earth of 0 to 10°C over the next forty years. Common sense indicates that the true value is almost certain to lie within this range, but the impacts of temperature changes within this range could vary from the trivial to the nearly catastrophic. The quality of this knowledge is low because it is of little assistance in determining whether preventive measures should be implemented or not.

Most regulatory decision making processes begin with the consideration of scientific knowledge (i.e., risk assessments). In this context, defining what is to comprise "knowledge", and what constitutes "quality", can be quite difficult. Krayer von Krauss *et al.* (2005) propose that "knowledge" should be interpreted rather broadly, as possibly encompassing (i) scientific knowledge, (ii) knowledge of the uncertainty characterizing the latter, (iii) indigenous knowledge, (iv) knowledge on the relevant normative biases and assumptions, and v) knowledge on alternative normative framings. von Schomberg (2004) points out that the notion of "quality" of information must be considered a "transformable normative standard", that is to say a standard of acceptability which will vary from one policy context to the other, depending on the issue at stake, the actors involved, etc. There can be no absolute definition of good or bad quality, and it is only possible to arrive at quality judgments through collective reflection and deliberation on the information available, in view of the policy context in which it is to be used. Klinke and Renn (2002) propose that in deliberative decision making processes, information about the uncertainty characterising scientific knowledge should be brought into a deliberative arena, the goal being to collectively determine the quality of the knowledge underpinning the regulatory decision (a process analogous to the *extended peer review* explained in chapter 1).

Scientists and engineers play an important role in supporting a systematic assessment of the quality of the information they provide to the decision-making process. In relation to the quality of computer models used to support regulatory decisions, Beck (2002) points out that quality assurance rests on: (i) whether the model has been constructed of approved hypotheses and theory; (ii) matching with history (i.e., classical calibration and validation); and (iii) whether the model is suited to its purpose. Krayer von Krauss *et al.* (2005) point out that model quality assessment should: identify a model that —

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[3] Adapted from British Standards Institution, BS 4778, London, 1979.

first and foremost — is suited to the purpose, yet bears — secondarily — some reasonable (not the unattainably perfect, but more, rather than less) resemblance to the 'real' thing.

The "fitness for purpose" invoked above is context dependent, and is therefore a matter to be determined through deliberation amongst scientists and the other actors of the policy community. However, the extent to which scientific input is comprised of approved hypotheses, theories and data, and the extent to which these are representative of the phenomena under consideration, are matters that, at least for the time being, are by and large determined by scientists. Typically, this type of quality assessment is enacted through uncertainty analyses conducted by the scientists performing the assessment, and peer reviews conducted by independent scientists. The W&H framework for uncertainty assessment has been proposed as a methodological contribution to the task of experts performing uncertainty analysis or peer review.

2.3 Uncertainty in decision support: a three dimensional concept

In order to understand how uncertainty manifests itself in scientific decision support, it is important to first consider the concept of uncertainty itself. Students in engineering and sciences are taught at an early stage how common problems such as sampling errors and imprecise measurements generate uncertainty in experimental results. This uncertainty is usually dealt with using statistical methods to express experimental results as confidence intervals.

An example of this type of uncertainty assessment could be the characterization of the uncertainty in an experiment aiming to measure the average amount of rainfall per year at a particular location. A number of sources of uncertainty exist in such an experiment. The rain gauge used to measure the amount of rainfall may not be very accurate, the researcher reading the rain gauge may make a mistake in doing so, and the amount of rain that falls at a given location will be different from one year to the next. To express this uncertainty, the results of such an experiment would be reported as a mean value, plus or minus a standard deviation, known as a confidence interval. Thus, a researcher may report with 95 % confidence that the average annual rainfall at a given location will be 30 mm/yr ± 4 mm/yr.

The question is: is this approach to assessing uncertainty sufficient to capture the uncertainty characteristic of policy relevant sciences? The answer is unfortunately *No*. In policy relevant sciences, different analysts will use different data and different methodological approaches, adopt different assumptions, and include different factors within the scope of their studies. Scientific knowledge of the underlying processes may evolve with time. Furthermore, the ethical values of different analysts will invariably influence the judgments that often must be made in the course of decision-support exercises. All of these factors represent sources of uncertainty which are difficultly communicated using the traditional, statistical approach to uncertainty assessment.

The W&H framework was born out of a desire to integrate the wide variety of terminology being used to describe uncertainty into a single coherent conceptual framework[4] . Walker *et al.*, (2003) adopt a broad definition of uncertainty, as being *any departure from the unachievable ideal of complete deterministic knowledge of the system*. At the core of the conceptual framework is the notion that uncertainty is best thought of as a three dimensional concept, including the i) *Location*, ii) *Level* and iii) *Nature* of uncertainty (as illustrated in Figure 2.1).

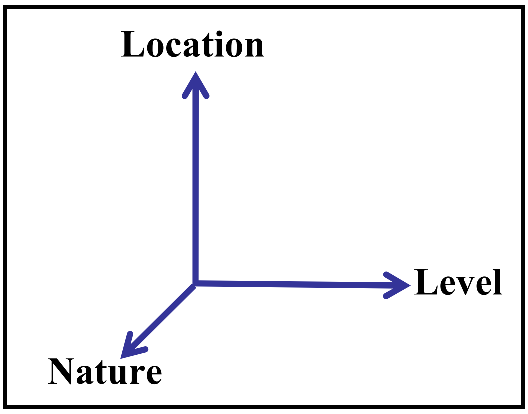

Figure 2.1 – The three dimensions of uncertainty. Source: Walker *et al.* (2003).

2.4 The location of uncertainty

To represent a problem, scientists use a combination of data, theory, and models. Similarly, all of the widely used approaches to scientific policy assessment rely on methodologies that can be considered idealized models, that is, abstractions of the real world issues under consideration. For example, *Risk* is modeled as a function of a system that includes *probability* and *consequence* subsystems. The group of cause-effect relationships encompassed by a scientific problem is referred to as the *system model* for the particular scientific problem. The *location* dimension refers to *where* uncertainty manifests itself within the configuration of the system model.

The notion of location of uncertainty can be illustrated by the example of a map of the world that was drawn by a European cartographer in the 15th century. Such a map would probably contain a fairly accurate description of the geography of Europe. Because the trade of spices and other goods between Europe and Asia was well established at that time, one might expect that those portions of the map depicting China, India, central Asia and the middle-east were also fairly accurate. However, as Columbus only ventured to America in 1492, the portions of the map depicting the American continent would likely be quite inaccurate (if they existed at all). Thus, it

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[4] Among recent papers and books directly or indirectly addressing the issue of characterizing uncertainty in decision support are: Alcamo and Bartnicki (1987), Beck (1987), Hodges (1987), Funtowicz and Ravetz (1990), Morgan and Henrion (1990), Rowe(1994), National Research Council (1996) , Shrader-Frechette (1996), Van der Sluijs (1997), Van Asselt (2000), Walker, Cave, and Rahman (2001), Van Asselt and Rotmans, (2002).

would be possible to point to the American continent as a "*location*" in the model that is subject to large uncertainty.

In a very similar manor, it is possible to pinpoint *locations* in decision support models that are subject to uncertainty. What are the health effects associated with exposure to a new kind of chemical? Until a wide variety of tests are performed, the answer to that question remains subject to much uncertainty. Thus, there is uncertainty at the "health effect" *location*.

The description of the model locations will vary according to the decision support method (model) that is being used. The locations identified in a cost-benefit analysis will be different from the locations identified in an environmental impact assessment. Nonetheless, it is possible to identify certain categories of locations that apply to most models. These are:

- Context
- Model structure
- Inputs
- Parameters
- Model outcome (result)

These categories will be discussed in more detail in the sections to follow.

2.4.1 Context

The "Context" location refers to the choice of the boundaries of the system to be modeled. This location is of great importance, as the choice of the boundaries of the system determines what part of the real world is considered inside the system (and therefore the model), and what part of the real world is left out. The choice of the system boundaries is often referred to as the "problem framing" or "problem definition". Uncertainty in the problem definition is an important cause for controversy in the regulatory debate (Jensen *et al.*, 2003; Meyer *et al.*, 2005). Different stakeholders have different perceptions of what constitutes a risk, which risks should be assessed, and how much risk is acceptable. For example, while some stakeholders may demand that all environmental impacts associated with a project be assessed, others may find it acceptable to only examine the potential impacts on certain endangered species.

2.4.2 Model structure

The term "model structure" refers to the variables, parameters and relationships that are used to describe (model) a given phenomenon. Model structure uncertainty is thus uncertainty about the form of the model that describes the phenomena included within the boundaries of the system. In situations where the system being studied involves the interaction of several complex phenomena, different groups of researchers may have different interpretations of what the dominant relationships in the system are, and which variables and parameters characterize these relationships. Uncertainty about the structure of the system implies that any one of many model formulations might be a plausible, although partial, representation of the system. Thus, researchers with competing interpretations of the system may be equally right, or equally wrong.

Figure 2.2 illustrates the distinction between context uncertainty and model structure uncertainty.

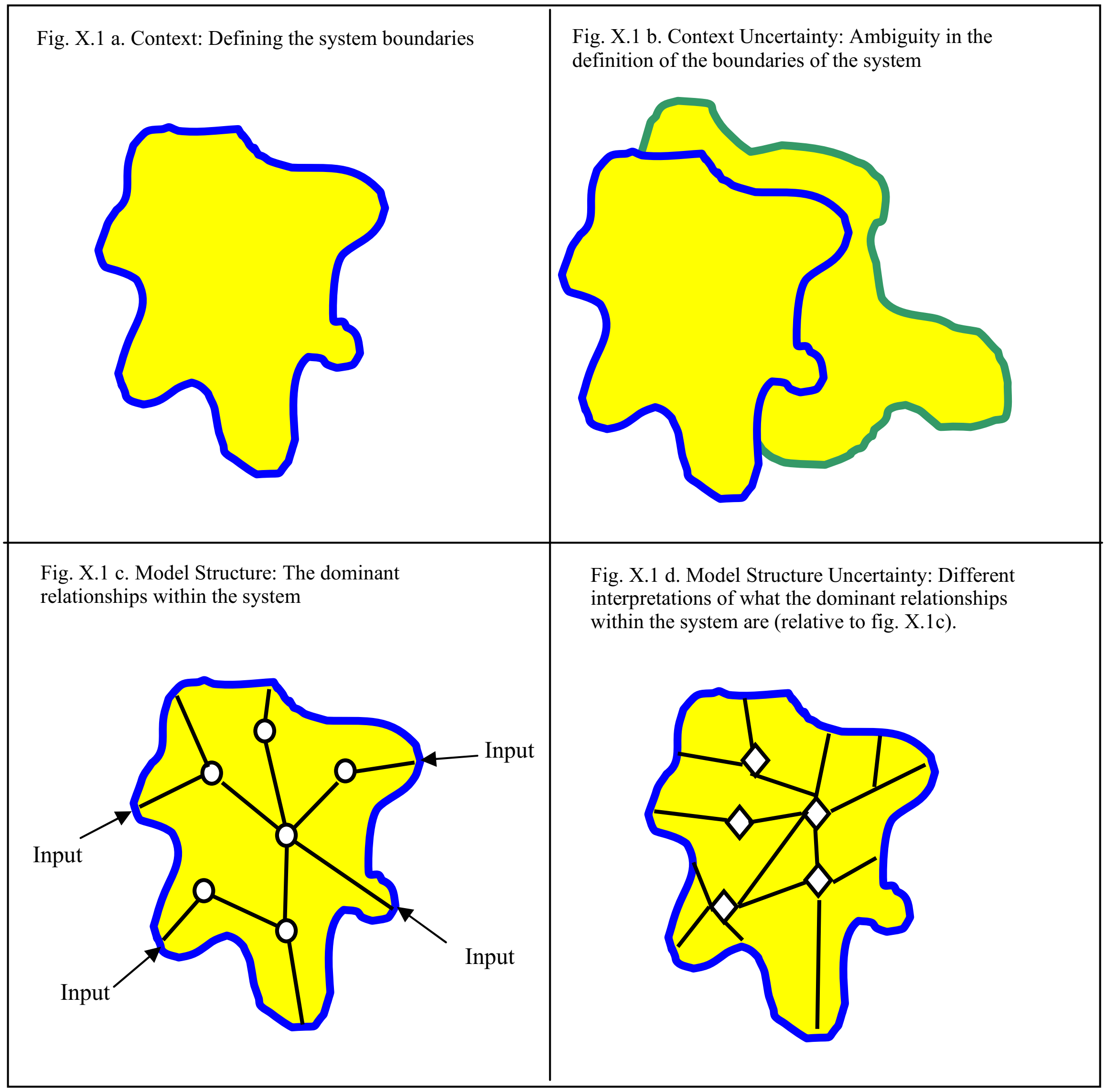

Fig. X.1 a. Context: Defining the system boundaries

Fig. X.1 b. Context Uncertainty: Ambiguity in the definition of the boundaries of the system

Fig. X.1 c. Model Structure: The dominant relationships within the system

Fig. X.1 d. Model Structure Uncertainty: Different interpretations of what the dominant relationships within the system are (relative to fig. X.1c).

Figure 2.2 – The Location of Uncertainty. Figs X.1a and X.1b illustrate the concept of *context uncertainty*, where ambiguity in the problem formulation leads to the wrong question being answered (also known as a Type III error). Figs X.1c and X.1d illustrate the concept of *model structure uncertainty*, where competing interpretations of the cause-effect relationships exist, and it is probable that neither of them is entirely correct. Input is illustrated as that which crosses the boundaries of the system (Source: Walker *et al.*, 2003).

2.4.3 Input

The "Input" location is associated with the data describing the system. Uncertainty about system data can be generated by a lack of sufficient amounts of data, by the fact that the data in hand is of poor quality, or by the fact that data describing the past is extrapolated to describe future conditions. Measurements can never exactly represent the “true” value of that which is being measured. Uncertainty in data can be due to sampling error, inaccuracy, imprecision in the measurements, conflicting data or simply lacking measurements.

The *sampling error* is an expression of the error associated with the degree of representativeness of the sample. The location, the time and the circumstances at which the sample has been taken may not be completely representative of those of the “true” value. The *inaccuracy* is the deviation from the “true” value that has been determined using a more accurate procedure, considered to provide the “true value”. In other words, inaccuracy refers to how close a measured value is to the value considered “true”. The *imprecision* is an expression of the variation of the measurements around a mean value. This is in fact a measure of the reproducibility of the result. The result of an experiment may consistently vary around a mean value, but be wrong compared to a "true" value.

2.4.4 Parameters

Parameters are constants in a model, supposedly invariant within a given simulation. The following types of parameters can be found:

- *Exact parameters* (e.g. π and e);
- *Fixed parameters,* (e.g. the gravitational constant g)*;*
- *A priori chosen parameters;*
- *Calibrated parameters.*

The uncertainty on exact and fixed parameters can generally be considered as negligible within the analysis. However, the extrapolation of parameter values from a priori experience does lead to parameter uncertainty, as past circumstances are rarely identical to current and future circumstances. Similarly, because calibrated parameters must be determined by calibration using historical data series and sufficient calibration data may not be available and/or errors may be present in the data that is available, calibrated parameters are also subject to parameter uncertainty.

2.4.5 Model outcome

This is the uncertainty caused by the accumulation of uncertainties from all of the above locations (context, model, inputs, and parameters). These uncertainties are propagated throughout the model and are reflected in the resulting estimates of the outcomes of interest (model result). It is sometimes called *prediction error,* since it is the discrepancy between the true value of an outcome and the model’s predicted value.

2.5 The level of uncertainty

The level of uncertainty is essentially an expression of the degree of severity of the uncertainty, as seen from the decision-makers perspective. While in some cases experts can express the uncertainty on their results in statistical terms, in other cases it is only possible for them to identify that scientific knowledge is limited in a given area, and the potential for surprise is therefore large.

The notion that uncertainty can manifest itself in different levels is illustrated by the example of climate change predictions provided earlier. The uncertainty involved in predicting the change in mean global temperature that can be expected for a given increase in the concentration of atmospheric CO_2 is small in comparison to the uncertainty involved in attempting to predict the myriad of changes that will occur as a result of this temperature increase. Will polar bears become extinct? Will costal cities be submerged? Are scientists even able to imagine all of the possibilities?

In accordance with a significant part of the body of literature on uncertainty (Knight, 1921; Smithson, 1988; Faber *et al.*, 1992; Wynne, 1992; ESTO, 2001), a scale containing different categories of levels of uncertainty is proposed, as shown in Figure 2.3 below.

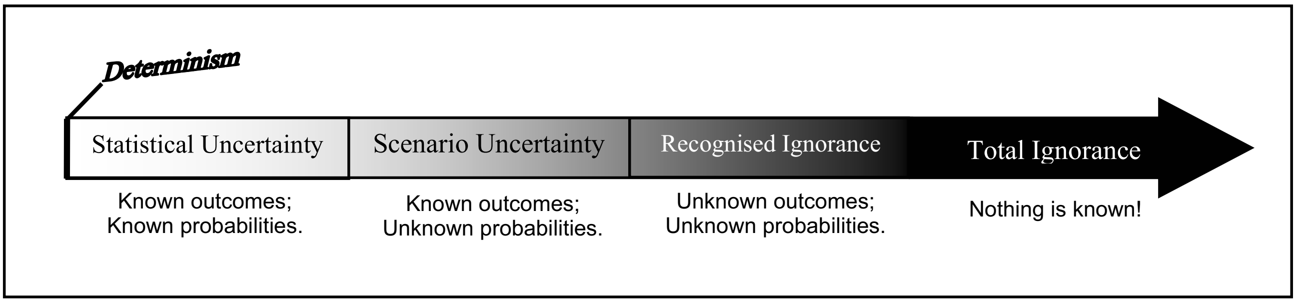

Figure 2.3 The levels of uncertainty (adapted from Walker *et al*, 2003).

The different levels of uncertainty will be discussed in more detail below. Although they are presented as discrete categories, it is often quite difficult to determine the level of uncertainty in such discrete terms, and it can therefore be helpful to consider the scale presented in Figure 2.3 as continuous.

2.5.1 Determinism and statistical uncertainty

Determinism is the situation in which everything is known exactly and with absolute certainty, an ideal that is never achieved in policy relevant sciences due to the complexity of the problems dealt with. On the scale of levels of uncertainty, it is at the end of the scale where there is no uncertainty whatsoever. *Statistical Uncertainty* describes the situation where there exist solid grounds for the assignment of a discrete probability to each of a well-defined set of outcomes, as illustrated in Figure 2.4. Potential outcomes can be identified as a finite set of discrete outcomes, or a single continuous range of outcomes (e.g. range in Figure 2.4). In situations of statistical uncertainty, analysts possessing knowledge of the form of the distribution (normal, lognormal, exponential, etc…) and its properties (σ, μ, etc…) can predict the probability with which any of the potential outcomes will occur.

As mentioned previously, the uncertainty characterising regulatory assessments is frequently reported in statistical terms. However, where this is the case, it cannot be interpreted as an expression of the fact that the assessment is characterised by statistical uncertainty only. Rather, it should be interpreted as a lack of attention to the deeper levels of uncertainty. As will be illustrated further on, many complex real-world policy problems involve deep uncertainties that cannot be adequately expressed in statistical terms. It is therefore misleading to express the uncertainty in policy relevant sciences only in statistical terms.

2.5.2 Scenario uncertainty

Scenario Uncertainty describes the state where the all of the possible outcomes are known, but where it is acknowledged that there exists no credible basis for the assignment of probability distributions to these outcomes, as illustrated in Figure 2.5. This can be due to the fact that the mechanisms leading to the potential outcomes are not well understood and it is, therefore, not possible to formulate the probability of any one particular outcome occurring.

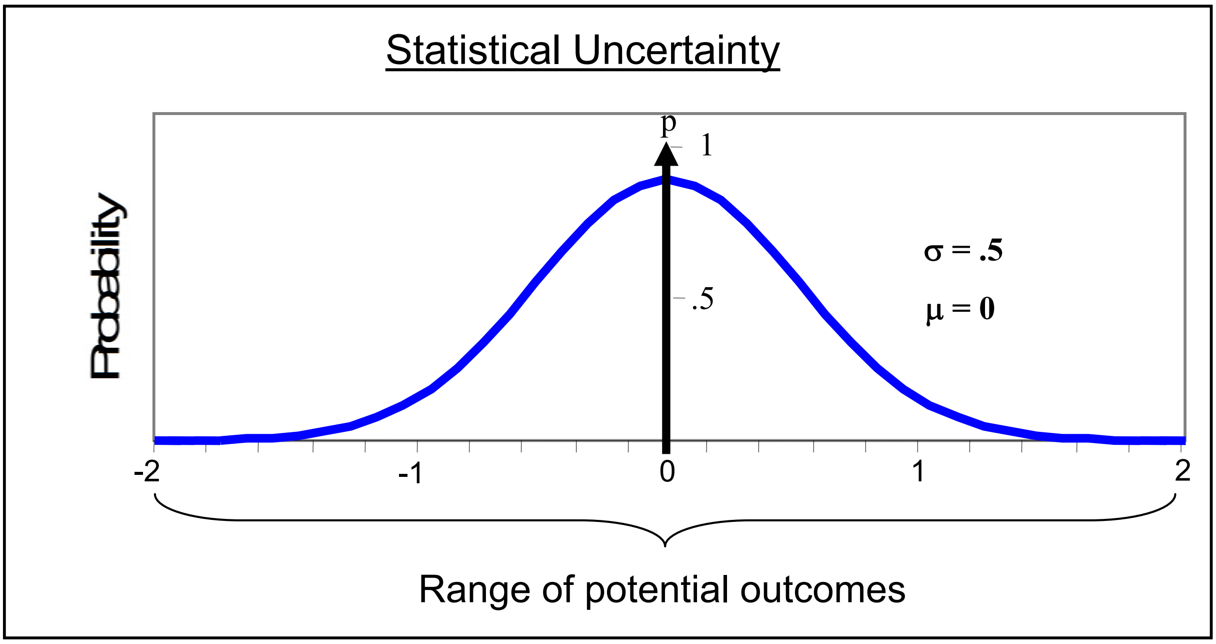

Figure 2.4 Statistical uncertainty: known outcomes, known probabilities.

Assumptions are a manifestation of scenario uncertainty. Decision support exercises often involve the use of scenarios in which a number of assumptions are made in order to simplify the problem being studied. In many cases, analysts do not have the time and/or data required to verify the validity of these assumptions. In some cases, verification may be practically or theoretically impossible. In many cases outcomes identified as being "improbable" by analysts are frequently left out of assessments in order to devote more resources to the analysis of outcomes deemed more likely (or about which more is known) (Patt, 1999).

An example that is useful in order to illustrate the notion of scenario uncertainty is that of the concerns raised over the use of antimicrobials or antibiotics in animal feedstuff (Edqvist and Pedersen, 2001). Antibiotics are probably the single most important discovery in the history of medicine. They have saved millions of lives by killing bacteria that cause diseases in humans and animals. Beginning in the 1940s, low levels of antibiotics began to be added to animal feedstuff as it was observed that this practice could increase the growth rate of the animals, increase the efficiency of food conversion by the animals, as well as have other benefits such as improved egg production in laying hens, increased litter size in sows and increased milk yield in dairy cows. Over the years, concerns developed over the potential for bacteria to develop resistance to the antibiotics. It was feared that the widespread use of the antibiotics would lead to the development of resistant bacterial strains, and that these antibiotics would therefore no longer be effective in the treatment of disease in humans. The scientific evidence available indicated that the development of bacterial resistance could take place, but how quickly and to what extent this could occur remain unknown to this day. The question of whether the short-term benefits outweigh the potential long-term risks is still being debated. In this case, the scenario is clear but the probability of its occurrence is unknown. The uncertainty here is of a level greater than *statistical uncertainty*, and is referred to as *scenario uncertainty*.

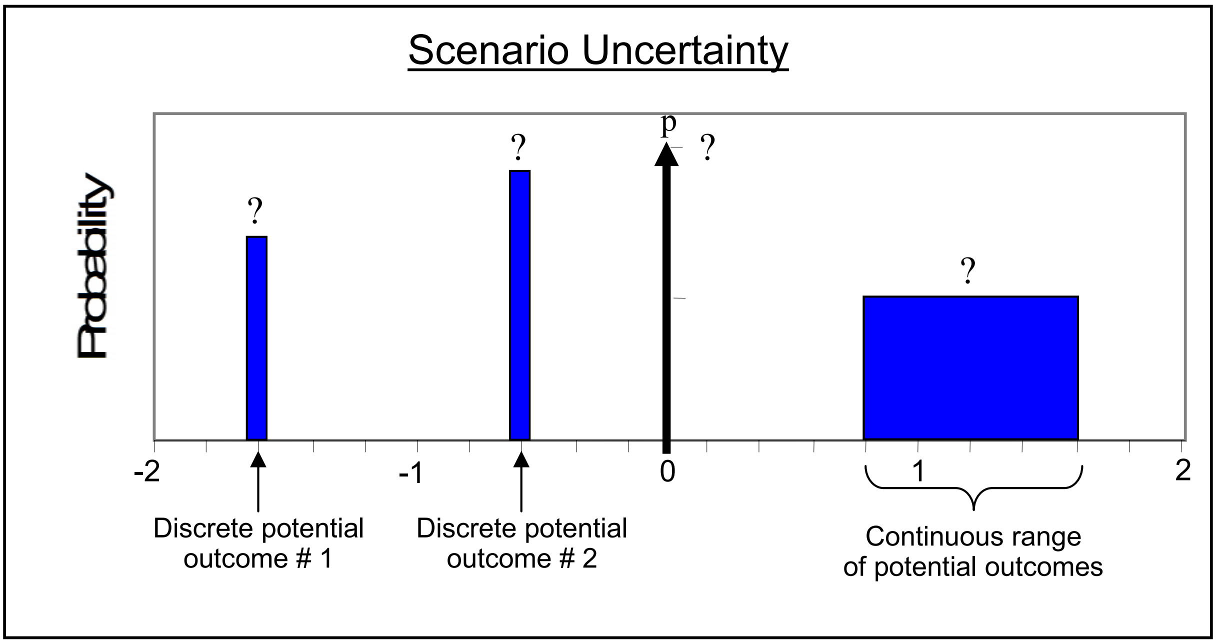

Figure 2.5 Scenario uncertainty: known outcomes, unknown probabilities.

2.5.3 Ignorance

Identified Ignorance describes the state where there exist neither grounds for the assignment of probabilities, nor even the basis for defining the complete set of potential outcomes. It is a state where fundamental uncertainty about the mechanisms and functional relationships being studied has been identified, and where the scientific basis for developing scenarios is weak. In some cases ignorance may be lessened by conducting further research, which implies that it might be possible to somehow achieve a better understanding. However, in cases where the functional relationships are very complicated and/or the number of parameters is very large, or in some cases where the relationships are inherently unidentifiable, due to e.g. chaotic properties in the system that make predictions impossible, neither research nor development can resolve the ignorance. This is referred to as *indeterminacy*. *Total ignorance* is the other extreme from determinism on the scale of uncertainty, which implies a deep level of uncertainty, to the extent that it is not even know that knowledge is lacking. In Figure 2.3, the continuing arrow at the end of the scale is used to indicate that there is no way of knowing the full extent of our ignorance.

An example of a policy problem in which, for a while, ignorance was the dominant level of uncertainty is that of the outbreak of Mad cow disease (also known as BSE) in Britain (van Zwanenberg and Millstone, 2001). In an effort to reduce costs and maximise the re-use of resources, it was common practice that the remains of sheep, cattle and other animals were recycled and used as a source of protein in animal feedstuffs. Following the diagnosis of the first cases of BSE in 1986, it was noticed that the pathological characteristics of the new disease closely resembled scrapie, a contagious disease common in the UK sheep population. Scrapie is a disease that attacks the brain of sheep, is untreatable and invariably fatal. Health authorities soon observed that contaminated feed was the principle cause of BSE in cattle. However, the question remained: contaminated by what? There was no scientific evidence that eating sheep meat from scrapie-infected animals could pose a health risk, and health authorities could not be sure that the agent that caused BSE had in fact derived from scrapie. Moreover, there was no scientific evidence indicating that BSE could subsequently be transmitted to humans in the form of Creutzfeldt-Jakob disease (CJD), and it was a big surprise when, in 1995, it was discovered that this could happen.

The notion of ignorance is illustrated by considering the uncertainty characterizing an assessment of the potential costs associated to BSE, performed at the time of the discovery of BSE in 1986. No historical data on BSE was available and scientific understanding of how the disease is contracted was limited. The extent of the public outcry that would eventually occur remained unknown, as did the extent of the loss of exports and the drop in domestic demand that ensued. Data on the relationship between BSE and CJD would not become available for another 10 years. In this context, any assessment would necessarily rely on a large number of assumptions and there would be no credible basis for the assignment of probabilities. Furthermore, at the time there was not even a credible basis to claim that all of the potential ramifications or costs (outcomes) of the BSE crisis had been thought of. The uncertainty characterizing this situation is a good example of *ignorance*.

2.6 The nature of uncertainty

Some phenomena, such as rainfall and other climatic processes, are inherently variable. Due to this variability, an exact description of the system will always remain unachievable, regardless of how much effort is invested into improving knowledge. In the case of other phenomena, the ability of scientists to study the phenomena is limited. The categories “epistemic uncertainty” and “stochastic uncertainty” are used to distinguish between the different *natures* of uncertainty, as follows:

- **Epistemic uncertainty**: uncertainty that is due to the imperfection of the knowledge of the system. This imperfection can be due to the inherent limits to knowing (e.g. indeterminate systems), or limitations in the methods available to study the system (e.g. inability to observe a phenomena due to lack of adequate observation instruments). In some cases, epistemic uncertainty can be reduced by more research or by improving study methods.
- **Stochastic uncertainty**: The uncertainty due to the inherent variability of some

of the phenomena included in the system. This variability is often encountered when considering human and natural systems. This variability can be described, but it is irreducible.

To illustrate the distinction between epistemic and stochastic uncertainty, it is worth re-considering the example of the experiment aiming to measure the average amount of rainfall per year at a particular location. In the initial example, three different sources of uncertainty were identified:

1. The rain gauge used to measure the amount of rainfall may not be very accurate;
2. The researcher reading the rain gauge may make a mistake in doing so;
3. The amount of rain that falls at a given location will always be different from one year to the next.

The first two sources of uncertainty identified above are due to imperfections in the methods used to study the phenomena. One could imagine that by using more sophisticated rain gauges, by increasing the number of samples taken and by being more careful in taking measurements, the uncertainty due to these two sources could be reduced. Because this uncertainty is due to limitations in knowledge, or limitations in the means we use to acquire knowledge, it is referred to as *epistemic uncertainty* (the word "epistemology" is derived from the Greek *episteme* "knowledge" and *logos* "reason").

The third source of uncertainty identified is different from the first two. No matter how many samples are taken, and no matter how sophisticated and precise the equipment used to do so is, uncertainty will always remain. This is due to the simple fact that the amount of rain that falls at a given location is a function of an overwhelming number of chaotic natural processes. These processes are inherently variable, and the amount of rain falling in a given location will therefore never be exactly the same from one year to the next. This uncertainty is referred to as *stochastic uncertainty*.

Determining the nature of the uncertainty present can be especially useful in deciding where to devote resources to reduce uncertainty. Where epistemic uncertainty is dominant, additional research, whether empirical study or theoretical research aimed at improving understanding, can potentially reduce uncertainty and thereby improve the quality of the output. However, where stochastic uncertainty is dominant, additional research is not likely to reduce uncertainty, and an adaptive implementation process may be the most effective way of moving forth.

2.7 Implications for the communication of uncertainty

The implication of the level dimension of uncertainty is that, from the point of view of the decision maker, the severity of the uncertainty identified increases as one progresses from statistical uncertainty through to identified ignorance. Only communicating statistical uncertainty, or communicating scenario uncertainty and ignorance in statistical terms, risks conveying a pretence of high certainty, when this is not actually the case. Thus, scenario uncertainty and identified ignorance should be communicated in qualitative terms, stressing the fact that the level of uncertainty is too high to provide a meaningful statistical description of uncertainty. Examples of qualitative descriptors of uncertainty will be provided in the chapters to come.

When communicating uncertainty amongst analysts familiar with the W&H framework, it could be useful to express the results of the uncertainty analysis in the form of an *uncertainty matrix*. The purpose of an uncertainty matrix is to provide a systematic and graphical overview of the location, level, and nature of the uncertainty associated with a policy assessment, as shown in Figure 2.6. The vertical axis identifies the **locations of uncertainty** – i.e., the different model locations characterizing a particular policy assessment. The first three columns of the horizontal axis cover the **level of uncertainty** in relation to all locations and the next two columns indicate the **nature of uncertainty** for each location.

Location	**Level**			**Nature**	
	Statistical Uncertainty	Scenario Uncertainty	Recognized Ignorance	Epistemic	Stochastic
Context					
Model Structure					
Inputs					
Parameters					
Model outcomes					

Figure 2.6 – Uncertainty matrix (Source: Walker *et al.*, 2003).

A further level of complexity can be introduced by considering the relative importance of a particular component (location) of the model to the output from the model. While for some component, a small error may result in a large change in the output from the model, in other cases, a large error may have only a small effect. This is generally referred to as the *sensitivity* of a model to a particular component. Either a quantitative (Saltelli *et al.*, 2000) or a qualitative sensitivity analysis (van der Sluijs, 1997; van Asselt, 2000) can be used to identify which uncertainties have the greatest impact on the outcomes of interest. The insights derived from such a sensitivity analysis are useful in determining where additional information or effort is most required and to allocate project resources accordingly.

2.8 Conclusion

The more complex, the more multi-disciplinary and the more uncertain a phenomenon appears to be, the more necessary deliberation about uncertainty is. Uncertainty assessment should be viewed as part of a greater process of quality control of policy relevant information. The W&H framework is an attempt to harmonize the terminology for characterizing uncertainty in policy relevant science. It suggests that uncertainty is a three dimensional concept defined by the location, the level and the nature of uncertainty. The W&H framework can be combined with other tools – for example, sensitivity analysis – to identify the most important locations of uncertainty. The framework can be applied in the initial assessment process or in the peer review process. Doing so can help clarify dissenting views and reveal that a case is characterised by more uncertainty than assessors had initially anticipated. Furthermore, it can yield guidance on whether or not it is appropriate to communicate uncertainty in statistical terms, in view of avoiding the creation of a pretence of certainty, when this is not the case.

Since its introduction, the W&H framework has been applied in the two empirical studies presented in chapters 3 and 4 of this dissertation, related to the uncertainty characterizing the risk assessment of genetically modified crops (Krayer von Krauss *et al.*, 2004; Krayer von Krauss *et al.*, in preparation). In addition, the W&H framework has been incorporated to the uncertainty management guidance system used at the Netherlands Environmental Assessment Agency (RIVM/MNP) (van der Sluijs *et al.*, 2003; Janssen *et al.,* 2005).

3 Uncertainty in the risk assessment of herbicide tolerant oilseed crops

3.1 *Introduction*

This chapter reports on the experiences gained in applying the W&H framework through expert elicitations aimed at obtaining qualitative and quantitative information regarding the uncertainty present in the environmental risk assessment of impacts on agriculture of genetically modified herbicide tolerant oilseed crops (canola). The interviews were conducted with leading canola experts during the spring of 2003. The results of these interviews were first reported in Krayer von Krauss *et al.* (2004).

3.2 *Background on the case study*

Genetic modification refers to the direct transfer or modification of genetic material using recombinant DNA techniques. One of the most widespread applications of genetic modification in agriculture has been to develop crops possessing the enzymatic capacity to break down a particular herbicide, effectively making the plants resistant to the herbicide. This modification can potentially simplify weed control by making it possible to apply herbicide onto fields in the early stages of crop growth, thereby eliminating weeds without damaging crop plants. Reducing competition by weeds improves crop yields.

There are currently three types of genetically modified herbicide resistant canola crops commercially available in North America: glyphosate tolerant (Round-Up Ready™) canola, glufosinate tolerant (Liberty Link™) canola, and bromoxynil tolerant (Navigator™) canola. As a case study, this investigation used the risk assessment of the glufosinate resistant Liberty Rape™ canola (line MS8/RF3), developed by AgrEvo and approved for market release in Canada and the EU in 1996, and in the US in 1998 (Agriculture and Agri-food Canada, 1996; Belgian Service of Biosafety & Biotechnology, 1997; USDA, 1999).

The uncertainty analysis focused exclusively on potential adverse impacts on agricultural and cultivation practices. The concern addressed by regulatory authorities in this regard is that herbicide tolerant volunteer plants (canola plants emerging as weeds in subsequent crops as a result of seed loss during harvest), and herbicide tolerant hybrids (plants resulting from cross-pollination between canola and its wild relatives), could lead to increased weediness, thereby creating a negative impact on agriculture and cultivation practices.

The Animal and Plant Health Inspection Service (APHIS) of the USDA conducted the agricultural risk assessment for the United States. The conclusion of the APHIS risk assessment was that Liberty Link canola "*will not have a negative impact on agricultural and cultivation practices*". The basis for this conclusion was first and foremost that mechanical means or alternative herbicides with different modes of action could be used to manage tolerant volunteers and hybrids, should they occur.

Furthermore, the seed bank parameters, fitness parameters and the sensitivity of volunteer plants to other herbicides would be similar to those of existing commercial varieties of rapeseed. APHIS hypothesized that the reduced seed dormancy of hybrids, the reduced fertility of these hybrids, and the absence of selection pressure for the herbicide tolerance trait outside of cultivation, would make it very unlikely that populations of the Liberty Link-hybrids would persist in the wild.

3.3 Selection of experts

The main criterion used to select the experts was their familiarity with the case study. The majority of the experts interviewed were Canadian. The first edible varieties of rapeseed were isolated in Canada in the 1960s and 70s. By now, canola has become Canada's third largest crop (after wheat and barley), and Canadian experts are among the world's foremost authorities on issues relating to canola. Canada was the first country to deregulate Liberty Link canola. All of the experts interviewed were either involved in research activities pertaining to canola, or in activities pertaining to the risk assessment of genetically modified canola. Some effort was made to examine an envelope of salient perspectives by drawing on expertise in both government and industry. Table I presents the affiliations and titles of the experts interviewed. The specific area of expertise of researchers is indicated in parentheses.

Table I Experts interviewed in this study (Source: Krayer von Krauss *et al.* (2004)).

Expert	Affiliation	Title (Expertise)
1	Agriculture and Agri-Food Canada	Research Scientist (Crop breeding)
2	Agriculture and Agri-Food Canada	Research Scientist (Weed resistance)
3	Agriculture and Agri-Food Canada	Research Scientist (Cytogenetics & biotechnology, crop breeding & diversification)
4	Agriculture and Agri-Food Canada	Principal Research Scientist (Plant systematics, crop & weed population biology)
5	Risø National Laboratory, Denmark	Senior Researcher (Hybrid cross compatibility & fertility, genetics)
6	Bayer Crop Science (formerly with AgrEvo Canada)	Director, Public and Government Affairs
7	Expert 7 preferred to withhold affiliation information	

3.4 Methodology

As mentioned in section 2.2 of chapter 2, the W&H framework is intended to be applied within an institutional context, in the course of the assessment process or the peer review process. It is envisioned that the uncertainty analysis would be performed by experts performing the regulatory assessment or a peer review thereof.

In the current PhD study, it was not possible to gain access to experts performing an actual risk assessment or peer review. This context was therefore simulated by having experts review a risk assessment study that had been conducted previously. The review took the form of an interview in which experts were asked a number of questions that implicitly reflected the concepts put forth in the W&H framework. The goal was to communicate the W&H framework and elicit the experts' knowledge of uncertainty, without intimidating or confusing the experts with an overwhelming number of new concepts. The interviews were conducted in five basic parts as follows:

i. Review of a proposed influence diagram;
ii. Assumptions analysis;
iii. Evaluation of empirical information;
iv. Surprise and ignorance analysis;
v. Assessment of level of uncertainty and sensitivity analysis.

3.4.1 Model locations and structure

The first part of the interview focused on the locations dimension of uncertainty. The goal was to inventory the important model locations for the risk assessment, as well as to identify disagreement as to which parameters and relationships (model locations) were important. Disagreement would be interpreted as a manifestation of competing model structures, which would indicate uncertainty on the model structure. To achieve this goal, the experts were presented with an influence diagram (5) (see Figure 3.1) illustrating the cause-effect relationship between the cultivation of the GM crop and the potential risk to agricultural and cultivation practices. The influence diagram was inferred on the basis of the risk assessment report published by APHIS (USDA, 1999).

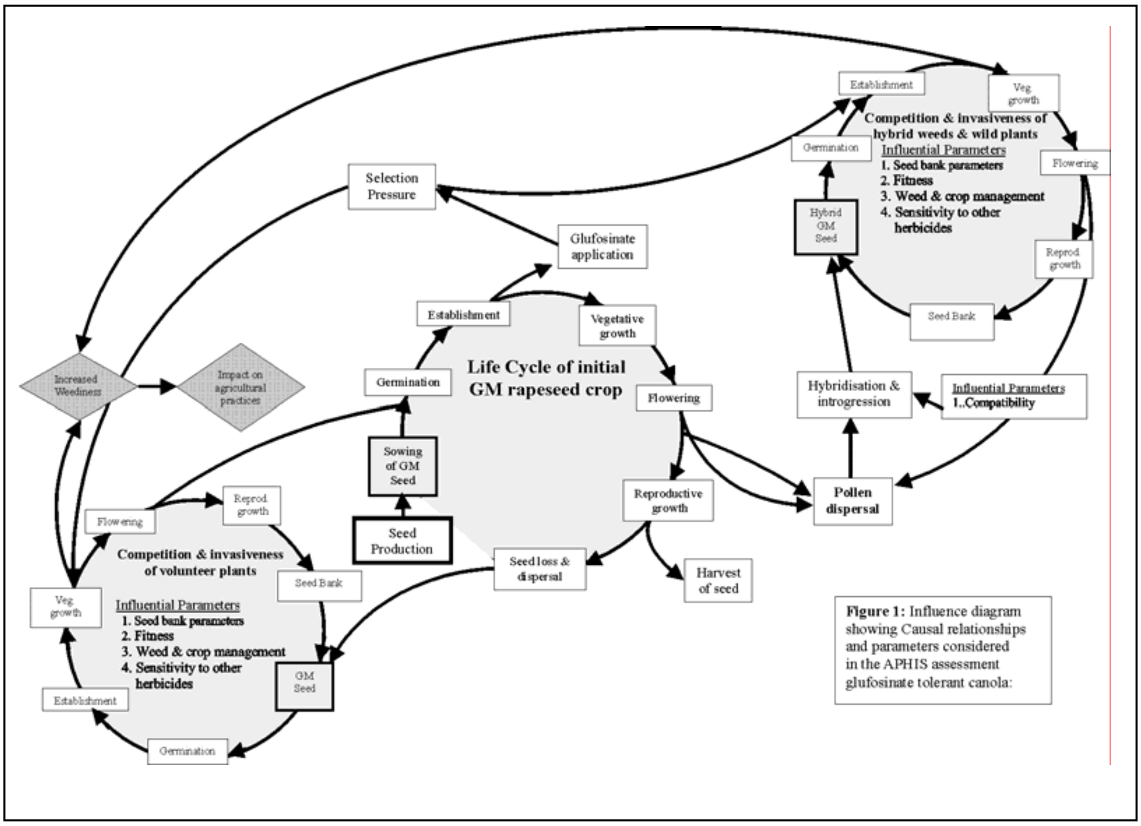

Figure 3.1. Influence diagram showing causal relationships and key parameters considered in the APHIS risk assessment. (Source: Krayer von Krauss *et al.* (2004)).

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(5) The influence diagram is based on un-published work performed in collaboration with K.H. Madsen, Royal Veterinary and Agricultural University, Denmark.

As such, it can be considered a representation of the mental model of the APHIS risk assessors. A detailed explanation of the influence diagram is provided by Krayer von Krauss *et al.*, (2004).

The diagram was explained to the experts, and they were asked to comment on whether the diagram mentioned all of the parameters and processes that they thought were key for evaluating the risk, and on whether they thought the diagram contained any superfluous elements.

3.4.2 Exploring uncertainty

The second, third and fourth parts of the interview were aimed at generating a dialogue on the various sources of uncertainty that could characterise the model locations identified in the first part of the interview. The goal was to raise the awareness of the experts to the various sources of uncertainty that can characterise a risk assessment, prior to proceeding to the assessment of the level of uncertainty in the fifth part of the interview.

As was explained in chapter 2 of this dissertation, assumptions are a frequent manifestation of scenario uncertainty. Thus, in the second part of the interview, the experts were presented with the conclusion of the APHIS risk assessment and the justification provided by APHIS for its conclusion. The experts were then asked to identify any assumptions implied by the conclusion reached. As in Risbey *et al.* (2001), the experts were asked to critic the validity of each assumption identified, and identify the potential consequences of the assumption being wrong.

In the third part, experts were asked to assess the quality of the empirical information upon which the conclusion of the risk assessment was based. In the APHIS risk assessment, four key considerations (model locations) were supported by reference to empirical investigations, these were: the sexual compatibility of the GM crop with wild relatives; the seed bank parameters of glufosinate tolerant volunteers and hybrids (seed germination, seed dormancy and seed production); the fitness of glufosinate tolerant volunteers and hybrids (pest and disease resistance characteristics, time to flowering and fertility); and the sensitivity of glufosinate tolerant volunteers and hybrids to alternative herbicides and mechanical means of weed control. The evaluation of data quality was based on the four different criteria contained in a pedigree matrix, a tool initially proposed by Funtowicz and Ravetz (1990). The pedigree matrix used in this study, illustrated in Table II, was developed by van der Sluijs *et al.* (2004) (see also van der Sluijs *et al.*, 2005).

The "proxy" scale evaluates how closely the quantity measured in practice resembles the actual variable about which information is desired for the purpose of the risk assessment. The "empirical" scale evaluates the degree to which direct empirical observations are used to produce data, as opposed to producing data by other means such as modelling. The "method" scale evaluates the quality of the methods used to gather the data, compared to the norm in the field. Finally, the "validation" scale refers to the degree to which efforts have been made to crosscheck the data against independent sources. Experts were asked to apply these scales to evaluate data quality in each of the areas for which APHIS cited information as the basis for its conclusion.

The evaluation was based on the expert's impression of the general "state of the art" at the time of approval (96-98), rather than on the specific studies cited by APHIS.

Table II. Pedigree criteria for evaluating data quality (from van der Sluijs *et al.*, 2004)

Score	Proxy	Empirical	Method	Validation
4	A direct measure of the desired quantity.	Controlled experiments and large sample; direct measurements.	Best available practice in well established discipline.	Compared with independent measurements of the same variable over long domain.
3	Good fit or measure.	Historical/field data, uncontrolled observations, small sample direct measurements.	Reliable method common within established discipline or best available practice in immature discipline.	Compared with independent measurements of closely related variable over shorter period.
2	Well correlated but not measuring the same thing.	Modelled/derived data, Indirect measurements.	Acceptable method but limited consensus on reliability.	Measurements not independent, proxy variable, limited domain.
1	Weak correlation.	Educated guesses, indirect approximation, rule of thumb estimates.	Preliminary methods with unknown reliability.	Weak and very indirect validation.
0	Not correlated and not clearly related.	Crude speculation.	No discernible rigor.	No validation performed.

In the fourth part of the interview, the surprise and ignorance analysis, the experts were asked a number of questions aimed at identifying potential indirect impacts that may not have been considered in the risk assessment, and identifying areas of the risk assessment where scientific knowledge is still very limited. Throughout most of the interview, the experts were asked to answer the questions from the perspective of a risk assessor performing an assessment at the time Liberty Link canola was originally approved (1996-98). The surprise and ignorance analysis was the only part of the interview where experts answered the questions from a current-day perspective.

3.4.3 Level and nature of uncertainty

The fifth part of the interview directly addressed the level and nature dimensions of the W&H framework. The experts were asked to quantify the level of uncertainty on key elements in the influence diagram, as well as the sensitivity of the conclusion of the risk assessment to changes in each of the key elements. The experts were also asked to identify the nature of the uncertainty. As explained in chapter 2 of this dissertation, that is if the uncertainty was mainly due to natural variability in the phenomena being observed (stochastic uncertainty), or if it was rather due to limitations in scientific knowledge (epistemic uncertainty).

In order to assess the level of uncertainty, a 0 to 1 scale was used. The scale, illustrated in Figure 3.2, was divided into the three broad categories put forth in chapter 2: statistical uncertainty; scenario uncertainty and identified ignorance. In the Figure, the main features of each category are indicated in the boxes under the scale. The categories were explained to the experts, and they were asked to assess the level of uncertainty that characterized each of the key parameters and processes in the influence diagram identified in part one of the interview.

In order to assess the sensitivity of the conclusion of the risk assessment to changes in the element being assessed, a second 0 to 1 scale was used, as illustrated in Figure 3.2. On the scale, a 0 implies that a large change in the element would have only a small effect on the conclusion, a 0.5 implies that a change would have a proportional effect, and a 1 implies that a small change would have a large effect. The scale was explained to the experts and they were asked to assess the sensitivity of the conclusion to changes in each of the key parameters and processes identified in the influence diagram. No guidance was given as to the interpretation of the terms "large" and "small", and the experts were therefore to make their own subjective judgment in this respect.

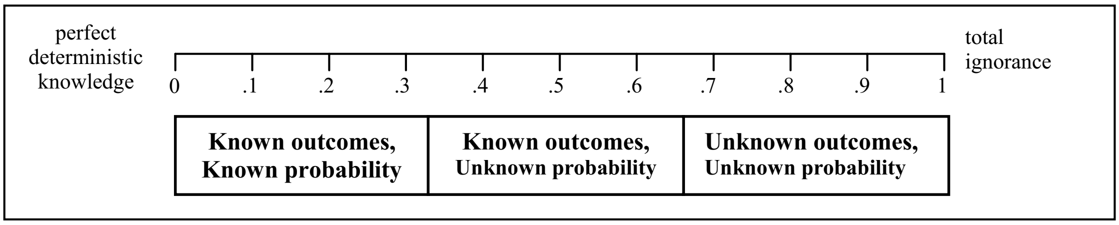

Figure. 3.2 The quantitative scale used to assess the level of uncertainty (Source: Krayer von Krauss *et al.* (2004)).

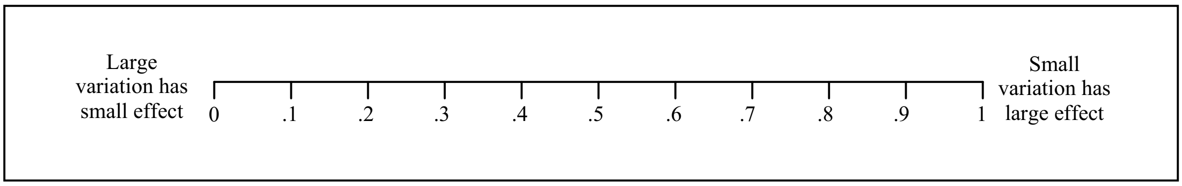

Figure. 3.3 The scale describing sensitivity of risk analysis conclusions to elements of the risk model (Source: Krayer von Krauss *et al.*, (2004)).

3.4.4 Consistency test

Finally, when time permitted (in 5 out of the 7 interviews conducted), a test was performed in order to verify how internally consistent the experts were in assessing the uncertainty level and the sensitivity associated with various elements of the influence diagram. Experts were given 100 poker chips and asked to allocate a fixed number of chips to each of the key elements of the influence diagram that they had assessed previously, to indicate how much they would be willing to invest to completely eliminate the uncertainty on that element of the influence diagram (which for internally consistent experts, should be roughly proportional to the influence of the uncertain diagram element on the conclusion of the risk assessment).

3.5 Results and discussion

3.5.1 Model locations and structure

The majority of the experts felt that the influence diagram shown in Figure 3.1 captured all of the processes and parameters they considered important to assessing the risk.

One expert pointed out that the diagram should also illustrate the fact that the seed lots for glufosinate tolerant canola can be contaminated by pollen carrying genes conferring tolerance to a herbicide other than glufosinate (e.g. glyphosate, also known as Round-Up™). In subsequent interviews, other experts questioned on the issue of seed lot contamination agreed that this was occurring with increasing frequency in practice. The practical implication of this particular instance of seed lot contamination is that affected farmers will find canola plants in their fields that are tolerant to more than one herbicide. The seeds from these plants could eventually lead to volunteer plants that are tolerant to more than one herbicide. Multiple herbicide tolerance makes it more difficult for farmers to control volunteer plants as it reduces the number of weed management options available to them.

Another expert pointed out that the glufosinate tolerance gene might increase the profit that individual farmers can earn from cultivating canola, which in turn may result in an increase in the total area of canola being grown. According to the expert, the effect of this increase should also be assessed, as it could lead to indirect impacts. An example provided by the expert was that canola requires a greater input of agro-chemicals than do cereals. None of the experts identified any superfluous items in the diagram.

3.5.2 Assumptions Analysis

Table III presents the two main assumptions identified by the experts. The second column contains a summary of the expert's opinion of the validity of each assumption, while the third column briefly describes the consequences that could occur if the assumptions turned out to be false.

Table III. Key assumptions identified by experts (Source: Krayer von Krauss *et al.*, 2004).

Assumption	Validity	Potential Consequences
Alternative herbicides and mechanical means of controlling herbicide tolerant volunteers and hybrids are available and will be used by farmers.	This is thought to be a good assumption. Alternative herbicides are available, especially if the follow-up crop is a cereal crop. Fewer alternatives are available if legumes or other broad leaf crops are grown in the following crop rotation. The presence of multiple tolerant volunteers also reduces the options available. In the case of mechanical means, these are available, but not favoured by farmers as they cost more.	Increased costs for farmers due to the additional costs imposed by volunteer control or the yield loss incurred due to competition by volunteers.
Fertility and dormancy of hybrids will be reduced, and therefore hybrids will not persist.	The validity of this assumption is difficult to determine. Although this was stated as a fact and supported with empirical data in the APHIS risk assessment, several experts pointed out that this is an area where the evidence is very weak and that it was an assumption that hybrids would not persist. One expert pointed out that some data now indicate that the fertility of hybrids is reduced to 50-60% in the first generation, but is restored to 90% in following generations.	Feral populations of hybrids could persist outside of cultivation, thereby leading to the existence of glufosinate tolerance gene pool in wild populations. Through cross-pollination, glufosinate tolerance genes could be spread both in agricultural and uncultivated settings.

3.5.3 Evaluation of empirical information

Table IV presents the results of the evaluation of empirical information on which the APHIS risk assessment was based, according to the pedigree criteria presented in Table II. Only point estimates were elicited. The first column contains the crucial information and the next four columns show the experts' assessment of how well these issues have been explored. Bold numbers are the average of all the responses. They are flanked by the lowest and the highest responses that were given. The last column shows the overall strength, a rather nebulous cross-row ranking tool, calculated as the sum of the scores shown in the first four columns, divided by the maximum total score achievable (i.e., divided by 16).

Table IV. Results of the evaluation of empirical information. Bold numbers are average response over all experts. They are flanked by the lowest and the highest single responses. "Proxy" refers to how closely the quantity measured in practice resembles the actual variable about which information is desired. "Empirical" means the degree to which direct empirical observations are used to produce data, as opposed to producing data by other means such as modeling. "Method" describes the strength of the methods used to gather the data, the gold standard being field observation. "Validation" is the degree to which efforts have been made to crosscheck the data against independent sources. Refer to Table II, above, for scoring guidelines (Source: Krayer von Krauss *et al.*, 2004)).

Empirical Information	Evaluation Scores				
	Proxy (0-4)	Empirical (0-4)	Method (0-4)	Validation (0-4)	Overall Strength (0-1)
1. Compatibility of GM crop with wild relatives	0 – **2.9** - 4	3 - **3.1** - 4	3 - **3.1** - 4	1 - **2.9** - 4	0.44 - **0.75** - 1
2. Seed bank parameters of glufosinate tolerant volunteers.	2 - **3.1** - 4	1 - **2.9** - 4	1 - **2.7** - 4	1 - **2.0** - 3	0.38 - **0.67** - 0.94
3. Seed bank parameters of glufosinate tolerant hybrids.	2 - **3.1** - 4	0 - **2.7** - 4	1 - **2.7** - 4	1 - **2.0** - 3	0.32 - **0.66** - 0.94
4. Fitness parameters of glufosinate tolerant volunteers.	1 – **2.8** - 4	1 – **3.0** - 4	1 - **2.4** - 4	1 - **2.0** - 4	0.32 - **0.64** - 1
5. Fitness parameters of glufosinate tolerant hybrids.	1 – **2.8** - 4	0 - **2.0** - 4	1 - **2.3** - 4	1 - **2.0** - 4	0.25 - **0.57** - 1
6. Sensitivity of glufosinate tolerant volunteers to alternative means of weed management.	3 - **3.8** - 4	2 - **3.4** - 4	3 - **3.9** - 4	1 - **3.2** - 4	0.56 - **0.89** - 1
7. Sensitivity of glufosinate tolerant hybrids to alternative means of weed management.	3 - **3.8** - 4	1 - **3.3** - 4	3 - **3.7** - 4	1 - **3.0** - 4	0.50 - **0.86** - 1

The results of the evaluation of the empirical information are in accordance with the observation made by some experts in the Assumptions Analysis, which was that the empirical information on the seed bank parameters and fitness parameters of hybrids was weak at the time of approval. A general trend seems to be that more and stronger information was available on volunteer plants than on hybrids at the time of approval. One expert explained that this was to be expected as only small numbers of hybrids occur in practice(6), making it difficult to obtain test specimens with which to perform research.

One expert mentioned that, in some cases, uncertainty arises due to lack of agreement amongst experts about the definition of certain key concepts, such as the fitness of a plant and how it should be measured.

An issue pointed out by several of the experts was that while risk assessors are interested in how the volunteers and hybrids will thrive in the agro-ecosystem, much of the data available at the time of the approval of Liberty Link canola resulted from small-scale, short-term greenhouse or field investigations. Because the conditions under which the tests are conducted may not be representative of the full array of relevant conditions, it can be difficult to generalize the test results. Similarly, most tests that had been performed, at the time, took place over the course of one plant lifecycle, and data from long-term, intergenerational tests were not available.

Finally, many experts pointed out that because of the experience gained in the time elapsed since the first herbicide tolerant canola crops were approved, they thought that stronger data is available today then was available at the time of approval.

3.5.4 Surprise and ignorance analysis

An important potential indirect impact that was identified by some of the experts interviewed is related to the potential impact of herbicide tolerant volunteers on agricultural and cultivation practices. As was pointed in the Assumptions Assessment, alternative herbicides are available to combat glufosinate tolerant volunteer plants. Farmers are not likely to incur significant additional costs as a result of glufosinate tolerant volunteers for the following reasons:

- It is common practice that fields are sprayed with the herbicide GLYPHOSATE prior to spring seeding, in order to eliminate all living plants from the field prior to the sewing of the new crop. (In the following discussion we will emphasize GLYPHOSATE with capital letters so the reader won't confuse it with glufosinate.)
- Most volunteer glufosinate tolerant plants present in the field will be eliminated by the GLYPHOSATE at this time. However, some seeds will likely remain dormant and germinate at a later time.
- Because in North America glufosinate is only registered for use on canola, and because canola is only grown every third year in the crop rotation, glufosinate tolerant plants emerging at any point during the intervening years would be sensitive to whatever herbicide is in use at the time, and would likely be eliminated. Thus, by the time a new crop of glufosinate tolerant canola is planted (3 years later), the bulk of the seed bank will have been

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(6) The elicitation took place prior to the publication of recent research where it is estimated that hybridization with some weedy relatives could yield up to 49,000 hybrid plants per year in the U.K. (Wilkinson *et al*., Science v.302 p.457-9. Oct 2003).

> depleted and glufosinate tolerant volunteers should not present a major problem.

However, a different scenario emerges when GLYPHOSATE tolerant volunteers are considered rather than glufosinate tolerant volunteers. Unlike glufosinate, GLYPHOSATE has a broad spectrum of permitted herbicidal uses. Because GLYPHOSATE tolerant canola volunteers will not be eliminated if only GLYPHOSATE is used in the spring pre-treatment, another herbicide (e.g. 2, 4-D, MCPA) would have to be mixed in with GLYPHOSATE in order to clear the field. This would entail additional costs for the farmer, it could have implications for the more environmentally benign form of agriculture known as no-till agriculture, as well as implications for the case-by-case basis upon which regulatory risk assessments of GMCs are currently conducted. An in-depth explanation of these implications is provided by Krayer von Krauss *et al.*, (2004).

Another issue pointed out by some of the experts interviewed was that while the APHIS risk assessment is concerned solely with the potential impacts due to increased weediness, no attention was given to indirect economic impacts that may be incurred as a result of the cultivation of herbicide tolerant canola. Due to the trade restrictions imposed by certain countries on genetically modified crops, the very fact that the canola is genetically modified may result in reduced revenues from exports. Furthermore, Canada is the world's largest exporter of mustard seed. Because canola and mustard are able to pollinate one-another, albeit at very low frequencies, there is a possibility that herbicide tolerance traits could contaminate mustard seeds destined for export, possibly leading to a reduced demand for Canadian mustard. In a similar vein, beekeepers may also see their products labelled genetically modified. It was also pointed out that specific farmer groups might suffer more damages than others. For example, some organic farmers may lose their certification and the associated economic premium in the event their crops are contaminated by pollen containing the herbicide tolerance trait.

On the issue of scientific ignorance, some experts raised the weak knowledge of the fate of the modified genetic material in the soil. The horizontal transfer of GM DNA to soil microflora is an area where scientific knowledge is particularly weak. Amongst other things, it is not known if the modified DNA could be transferred horizontally to the microbial community, or what ramifications this could have.

It is interesting that no expert mentioned unidentified ignorance: the yet unknown or unsuspected negative impact(s), the set of causal linkages that science has not yet put together, the surprise scenario that motivates precautionary thinking. This may be due to the well-documented phenomenon of expert overconfidence (Morgan and Henrion, 1990), or perhaps to prudent aversion to venturing outside of the expert's domain of expertise. However, it may also point to an important difference between risk analysts and their audience. The risk analyst must summarize the best available knowledge and make a recommendation on this basis, while the audience does not necessarily agree that available knowledge is sufficient.

3.5.5 Level and nature of uncertainty

Figure 3.4 summarizes three qualities of the uncertainty surrounding 7 key model locations for the risk assessment for glufosinate resistant canola: the "level" of uncertainty (using the scale described in Figure 3.2), the "sensitivity" of the assessment to the element (Figure 3.3) and the "influence" of this uncertainty, which was calculated by taking the square root of the product of the level and the sensitivity ($I = (L \text{ x } S)^{\frac{1}{2}}$).

Figure 3.4 is divided into eight categories, all pertaining to model locations for the influence diagram that was shown to the experts:

1. Choice of the processes;
2. Choice of the parameters;
3. Knowledge of weed and crop management practices;
4. Knowledge of compatibility of GM crop with wild relatives;
5. Knowledge of seed bank parameters of herbicide tolerant (HT) volunteers and hybrids;
6. Knowledge of fitness parameters of herbicide tolerant volunteers and hybrids;
7. Knowledge of sensitivity to alternative means of weed management;
8. Overall conclusion of the risk assessment.

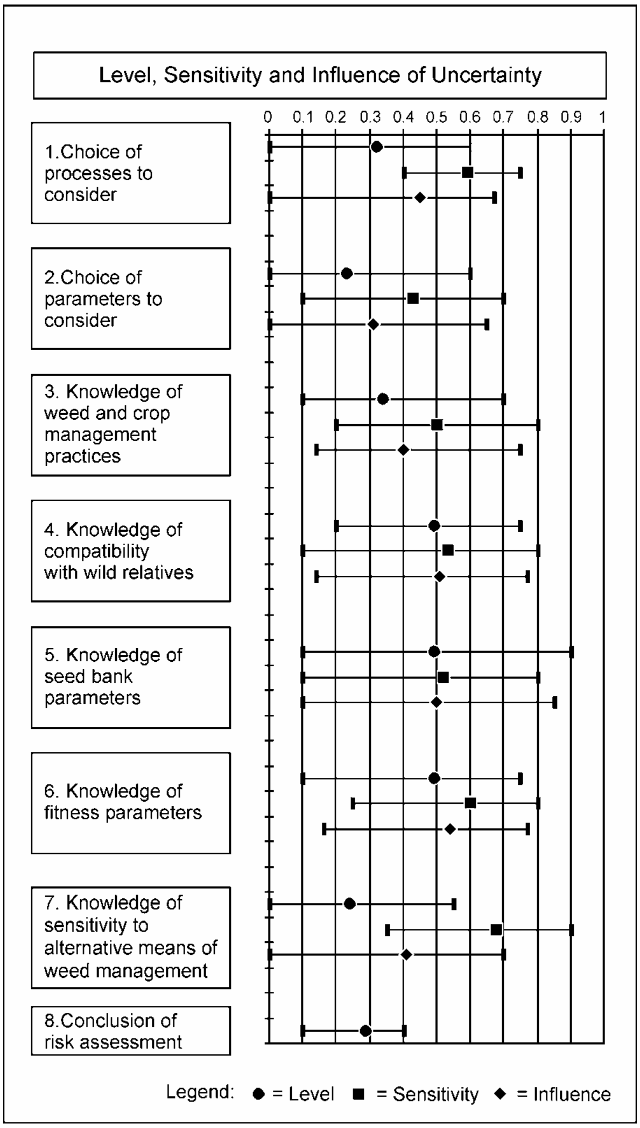

Figure 3.4 Results of Quantitative Assessment of Level, Sensitivity and Influence of Uncertainty ($I = (L \text{ x } S)^{\frac{1}{2}}$). Only point estimates were elicited. Solid symbols denote the average of the 7 individual point estimates obtained. They are bounded on the left by the lowest, and on the right by the highest values that were elicited (Source: Krayer von Krauss *et al.*, (2004)).

The first two categories in the Figure focus on the context and model structure locations. They illustrate the results for the "choice of the processes" and the "choice of the parameters" to include in the influence diagram (i.e., to consider in order to assess the risk). The aim of these questions was to determine the level of uncertainty characterizing the choice of which processes and parameters are important to consider in the cause-effect relationship leading to the potential impact. The next five categories in Figure 3.4 deal with the parameters considered influential in the risk assessment: the weed and crop management practices observed by farmers; the compatibility of the GM crop with wild relatives; the seed bank and fitness parameters of tolerant volunteers and hybrids; and the sensitivity of tolerant volunteers and hybrids to alternative means of weed management. For each of these parameters, the Figure shows the level of uncertainty characterizing expert knowledge of the parameter, how sensitive the conclusion of the risk assessment is to changes in the value of the parameter, and what the influence of the uncertainty is on the conclusion? Finally, the last category in Figure 3.4 shows the level of uncertainty characterizing the overall conclusion of the risk assessment. Again, only point estimates were elicited from the experts. In the Figure, the solid symbols denote the average of the individual point estimates obtained. They are bounded on the left by the lowest, and on the right by the highest values that were elicited.

Table V shows the results of the assessment of the "Nature" of uncertainty. Here "stochastic uncertainty" is uncertainty due to the inherent variability of the phenomena being considered, and epistemological uncertainty is due to a lack of knowledge. The values shown in the Table indicate the number of experts who thought that the uncertainty they had identified was predominantly due to the type of uncertainty in question (variability or epistemological uncertainty). The results suggest that additional research could potentially reduce the uncertainty surrounding the compatibility of the GM crop with wild relatives and the fitness parameters of herbicide tolerant volunteers and hybrids. The reason that not all rows sum to 7 is that some experts preferred not to express themselves on issues clearly outside their field of expertise

Table. V Results of the assessment of the Nature of uncertainty, the number of experts describing an uncertainty as predominantly due to variability or lack of knowledge (Source: Krayer von Krauss *et al.* (2004)).

Element of Influence Diagram	Stochastic Uncertainty	Epistemological Uncertainty
1.Choice of processes to consider (model structure)	3	3
2.Choice of parameters to consider (model structure)	5	1
3.Weed and crop management practices	6	1
4.Compatibility with wild relatives	2	5
5.Seed bank parameters	4	2
6.Fitness parameters	2	5
7.Sensitivity to alternative means of weed management	3	2

As can be seen in Figure 3.4, the highest levels of uncertainty were attributed to the knowledge of the parameters "compatibility with wild relatives", "seed bank parameters" and "fitness parameters". This is consistent with the results of the Assumptions Analysis and the Evaluation of Empirical Information, which both indicated that more research was needed on the ability of potential hybrids to perpetuate themselves. This would seem to be supported by the results shown in Table V, where it can be seen that epistemological uncertainty is dominating in the case of the parameters "compatibility with wild relatives" and "fitness parameters". This indicates that the majority of the experts felt that the uncertainty that they had identified in these areas was predominantly due to a lack of scientific knowledge.

The results of the sensitivity assessment indicate that the experts think that the parameter “sensitivity [of tolerant volunteers and hybrids] to alternative means of weed management” is one of the most critical parameters for the conclusion of the risk assessment. This essentially means that if alternative weed management methods proved to be ineffective at controlling glufosinate tolerant volunteer plants, there would be an impact on agricultural and cultivation practices. In Table V, it can be seen that a large majority of the experts interviewed considered that the uncertainty characterizing weed and crop management practices is dominated by variability. This is consistent with the fact that this parameter is highly dependent on human behaviour, which is known to be very variable.

In Figure 3.4, it is interesting to note that while the experts tended to rate the uncertainty around many of the individual model locations to be in the mid-range of the Level scale, they nonetheless rated the uncertainty of the overall conclusion of the risk assessment to be in the low range of the Level scale. It can also be seen that in most cases there is a wide range between the lowest and the highest responses received, which is indicative of the diversity of expert opinions on particular issues. This diversity is not unusual for expert elicitation. As has been observed in other expert elicitation studies (Morgan and Keith, 1995; Keith, 1996; Stirling and Mayer, 2001), the quantitative results of the elicitation display a much richer diversity of expert opinion than the risk assessments published by regulatory authorities.

For a variety of reasons, different experts can interpret the same question differently. Many of the tools used to assess uncertainty, for example the scale used to assess the Level of uncertainty, were new to the experts. Although care was taken to explain the Level scale to the experts before they responded, the novelty of the concepts involved may have lead some experts to ignore the distinctions between the categories on the scale and simply respond with a scale rating based on some personal scale. Similarly, it cannot be ruled out that ambiguity in the questions may have lead to different interpretations, or that personal biases may have had an influence.

Future investigations may reduce interpretive flexibility by further characterizing the terminology used, e.g. by using generic descriptive formula to describe terms such as ‘large’ and ‘small’. As well, the sample of experts could be expanded in order to focus explicitly on documenting the diversity of expert opinion. In the present study, the expert sample included seven experts, four of whom are research scientists employed by Agriculture and Agri-Food Canada. The presence of additional experts from other organizations (e.g. academia, regulatory agencies, interest groups, and growers) would provide a more complete picture of the diversity of opinions. Increased focus on documenting the diversity of opinion may also make it possible to determine to what extent divergences of opinion might be artefacts of research design (for instance relating to inconsistent interpretations or framings), or to what extent these might sustain a conclusion that underlying collective uncertainties significantly exceed those typically entertained by individual experts.

Figure 3.5 shows the mean and variance of the responses given by each expert on the questions pertaining to the level of uncertainty. As can be seen in the Figure, some experts consistently rated the level of uncertainty to be on the lower end of the scale (known outcomes, known probability), while the majority consistently rated the level of uncertainty to be in the mid-range (known outcomes, unknown probability). The fact that individual experts varied their responses only relatively little may be due to the perspective each of the experts has on uncertainty, but it may also be due to a phenomenon known as "anchoring". Anchoring is the phenomenon whereby experts tend to unduly favour a particular value, for example the first value given or a conventional value (van der Sluijs *et al.,* 1998). None of the experts seemed to be worried about unknown outcomes (Level ≥ 0.7). This could be attributable to a fear of appearing ignorant, or less of an expert, on behalf of the experts.

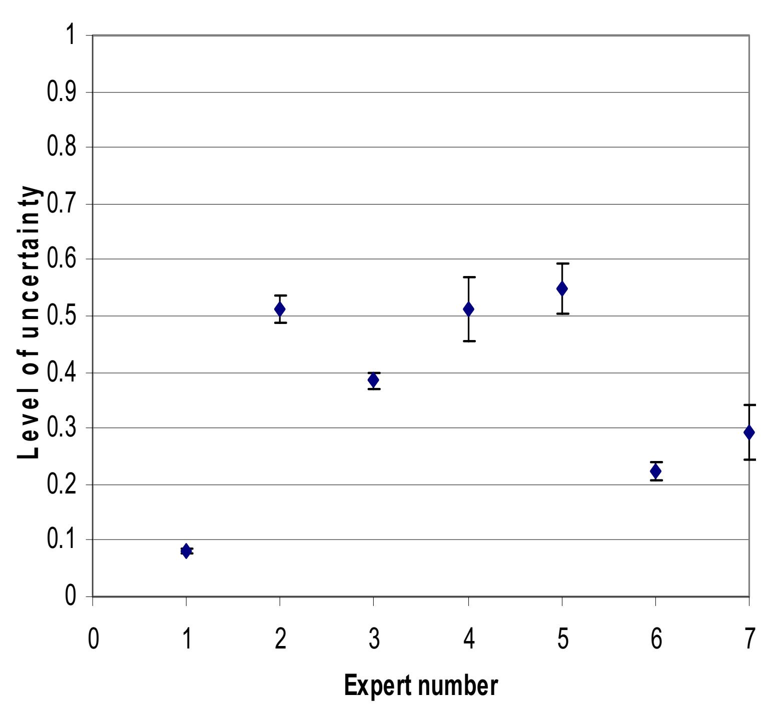

Figure 3.5 Mean and variance of the responses of individual experts on the level of uncertainty (Source: Krayer von Krauss et al., 2004)).

3.5.6 Consistency

To a certain extent, consistency tests can be used to test the degree of comprehension the experts had of the questions they were asked. Figure 3.6 illustrates the results of the consistency tests that were performed on some of the experts interviewed, in the form of an index of uncertainty influence versus the willingness to pay to eliminate uncertainty. Willingness to pay is based on the number of poker chips the experts were willing to "invest" into research on a particular element of the influence diagram in order to eliminate the uncertainty on that element. One hundred chips were given to the experts to apportion among research needs. A consistent expert would be expected to allot more chips to elements for which the influence of uncertainty is large (i.e., high levels of uncertainty and sensitivity), and for which he/she considers the uncertainty to be reducible. As can be seen in Figure 3.6, aside from the fact that experts were generally willing to invest more into research on model components where epistemic uncertainty dominated, consistency was not a major feature of the responses given by the experts. This could be an indication that the experts did not fully understand the questions they were asked, or that they based the allotment of their chips on decision criteria other than the influence of uncertainty, e.g. personal research interests or their estimate of the expected return on the investment. Experts understand the research opportunities in their own area best, and have a vested interest in wanting to pursue them.

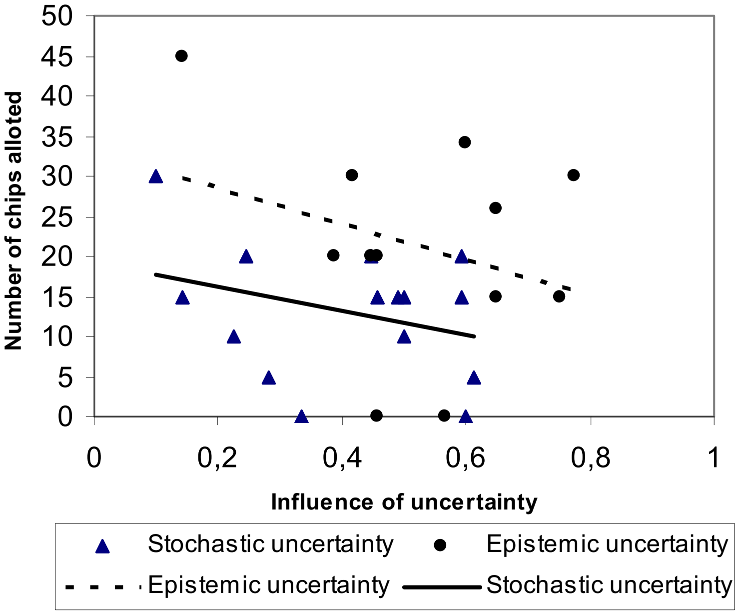

Figure. 3.6 Consistency index between influence of uncertainty and willingness to pay to eliminate uncertainty.

Although the methodology used in this investigation and the results reported should contribute to fostering a constructive dialogue on uncertainty in the risk assessment of GM crops, it is unlikely they will suffice to address the main public concern in relation to GMOs – the unanticipated catastrophe. While this assessment focused primarily on “known” uncertainties, public concern focuses instead on the acknowledged and unacknowledged limitations of science and the belief that scientific reversals are bound to occur (Levy and Derby, 2000; Wynne *et al.*, 2000; Jiles, 2003). The public looks retrospectively at scientific claims and remembers the ones that didn’t prove true (such as radiation and DDT are harmless). This reinforces their scepticism, especially when the consequences are perceived as irreversible and potentially grave. Because of this, it is not likely that the mere act of performing uncertainty analyses such as this one will suffice to address public concerns about the risks of GMCs. Nonetheless, the results obtained are a good starting point for deliberation on the uncertainties in risk assessments of GMCs. Furthermore, by including a broader diversity of stakeholders in the study, a broader range of perspectives may be made obvious.

Scientific uncertainties can be managed by conducting basic research, by implementing rigorous monitoring programs, and by re-assessing individual cases as new information becomes available. For this to occur, policy makers must be aware of uncertainty and develop their policies accordingly. Explorations of the scientific and economic uncertainties associated with regulatory decisions on GMOs, such as the work presented here, should help to reduce public concerns. Issues uncovered in such explorations could contribute to identifying goals for long-term monitoring programs and clarifying research priorities. Furthermore, cross-expert uncertainty analyses such as the one performed here could provide structure to characterizations of uncertainty such as those required by EU directive 2001/18/EEC.

3.6 Conclusion

The results of the uncertainty analysis reveal three issues of potential concern that are currently left outside the scope of the risk assessment of herbicide tolerant oilseed crops. These are the potential loss of the agronomic and environmental benefits of GLYPHOSATE due to the combined problems of herbicide tolerant canola and wheat volunteers, the growing problem of seed lot contamination, and potential market impacts. The results also draw attention to two areas where knowledge is lacking, which are: the occurrence of hybrids between canola and wild relatives and the ability of the hybrids to perpetuate themselves in nature; and the fate of the herbicide tolerance genes in soil and their interaction with soil micro fauna. These results should be helpful in establishing goals for long-term monitoring programs, in setting research priorities, and in increasing the transparency of the risk assessment process.

Future investigations may reduce interpretive flexibility by further characterizing the terminology used, e.g. by using generic descriptive formula to describe the various levels of uncertainty on the levels axis. As well, the sample of experts could be expanded in order to focus explicitly on documenting the diversity of expert opinion.

The experts who participated in this study did not dwell on “surprise” outcomes. This is in contrast to the alleged public preoccupation with risks as yet unidentified. Because of this, it is not likely that the mere act of performing uncertainty analyses such as this one will suffice to address public concerns about the risks of GMCs. Nonetheless, the results obtained are a good starting point for deliberation on the uncertainties in risk assessments of GMCs. Furthermore, by including a broader sample of stakeholders in the study, a broader diversity of perspectives may be documented, which could highlight additional areas of ignorance.

4 Uncertainty characterising the knowledge of Transgene Silencing

4.1 Introduction

The goal of this chapter is to illustrate the application of the W&H integrated uncertainty analysis framework through expert elicitations aimed at obtaining qualitative and quantitative information on the uncertainty characterizing a basic scientific problem: transgene silencing in genetically modified plants. The elicitations were conducted during the spring of 2005, and the results will be reported in Krayer von Krauss *et al.*, (in preparation).

4.2 Background on the case study

In genetic engineering, alien genes, referred to as transgenes, are inserted into conventional plant species to create genetically modified plants. The level at which the transgene is expressed in the new plant (i.e., the transformant) is unpredictable and varies from one transformant to another. Sometimes the newly inserted transgenes are not expressed at all. This can be due to a phenomenon referred to as *transgene silencing*. Transgene silencing is an interesting phenomenon for several reasons. First, the mechanisms underlying transgene silencing are still not completely understood by scientists (Matzke *et al.*, 2004; Schubert *et al.*, 2004; Fagard and Vaucheret, 2000; DeBlock and Debrouwer, 1993), thereby highlighting the limitations in knowledge of how genes operate when they are placed into a new genome. Second, there are situations where transgene silencing can be unfortunate, e.g. in the case where, in order to avoid the transfer of transgenes via pollen spread, plants have been modified to make them sterile (Doerfler *et al.*, 1997). In this case, silencing of the gene that causes sterility leads to the production of pollen, which could then lead to the unwanted spread of transgenes to wild or non-transgenic plants. Different levels of gene expression may disrupt the cell metabolism, hence causing changes in the functional properties of the organism (Inose and Murata, 1995). Potential secondary effects include changed levels of bioactive compounds in the organism and altered levels of antinutrients as well as potential allergens and toxins (Lappé *et al.*, 1999; Novak and Haslberger, 2000). Under the recent EU legislation on the risk assessment of genetically modified organisms (2001/18/EEC), gene silencing is considered a mechanism that can lead to the occurrence of adverse effects and the stability of the transgene should therefore be reported on in the approval process (2002/623/EC).

4.3 Selection of experts

The main criterion used to select the experts was their familiarity with the case study. All of the experts interviewed were either currently involved in research activities pertaining to transgene silencing, or had been within the recent past. Table VI presents the affiliations of the experts interviewed as well as key words describing their area of expertise. Although some effort was made to examine an envelope of salient perspectives by drawing on expertise in both academia and industry, only researchers from academia responded to the invitation to participate in the study. Two representatives of a non-profit, public interest research organization were consulted informally in order to receive feedback on the study design and identify their concerns in relation to transcriptional gene silencing. Unfortunately, they did not feel that their level of expertise on the specific topic of transcriptional gene silencing was sufficient for them to be considered "experts" in the context of this study.

Table VI Experts interviewed in this study. (Source: Krayer von Krauss *et al.* (in preparation)).

Experts	Affiliation	Expertise
1	Matzke Lab, Gregor Mendel Institute for Molecular Plant Biology, Austria	RNA silencing, epigenetics, DNA-methylation, Arabidopsis
2	Molecular Plant Virology Group, Institute of Botany, University of Basel, Switzerland	Molecular biology, virology, biotechnology, plant research
3	Molecular Plant Virology Group, Institute of Botany, University of Basel, Switzerland	Plant molecular biology, virology, silencing, epigenetics, biotechnology.
4	Institute of Cell and Molecular Biology, University of Edinburgh, Scotland	Transgene silencing, control of transgene expression, histone methylation, gene regulation, plant development.
5	Laboratory of Phytopathology, Wageningen University, The Netherlands	Plant pathology, Arabidopsis biochemistry, proteasis.
NGO Representatives		
1	EcoNexus, Brighton, United Kingdom	Plant biology, molecular biology, virology, genetics and RNA biology
2	EcoNexus, Brighton, United Kingdom	Plant biology, plant molecular genetics, *Arabidopsis*

4.4 Methodology

The methodology adopted in this study was very similar to the one presented in section 3.4. As in Krayer von Krauss *et al.* (2004), the institutional context (i.e., uncertainty analysis or peer review on a decision support study) in which the W&H framework is intended to be applied was simulated by having experts respond to a number of questions that implicitly reflected the concepts put forth in the W&H framework. Here again, the goal was to communicate the W&H framework and elicit the experts' knowledge of uncertainty, without intimidating or confusing the experts by an overwhelming number of new concepts.

Each interview was conducted in four basic parts as follows:

i. Review of a proposed influence diagram (system model);
ii. Assessment of level and nature of uncertainty;
iii. Further description of uncertainty;
iv. Surprise analysis;
v. Consistency test.

4.4.1 Model locations and structure

The first part of the interview focused on the locations dimension of uncertainty. The goal was to inventory the important model locations, as well as to identify disagreement regarding the model locations, in view of diagnosing model structure uncertainty. The experts were presented with an influence diagram (see Figure 4.1) illustrating the cause-effect relationships scientist suspect are involved in transgene silencing. The diagram was developed by inferring on the basis of scientific journal articles, as well as with the assistance of an expert in the field [7].

Scientists distinguish between two different types of gene silencing: transcriptional gene silencing (TGS) and post-transcriptional gene silencing (PTGS). TGS results from the inactivation of the promoter (T-DNA), while PTGS occurs when the promoters are active and the genes transcribe, but the mRNAs fail to accumulate. In order to simplify the case study, the choice was made to focus mainly on TGS. However, as can be seen in Figure 4.1, the two phenomena are related to one-another and to some extent, one cannot avoid discussing PTGS, as scientist suspect that it may influence the occurrence of TGS. Figure 4.1 illustrates the three principle causal pathways scientists suspect lead to the occurrence of TGS:

- Repeat-induced DNA methylation;
- Chromosomal environment of the transgene;
- Influence of Post-transcriptional gene silencing (PTGS).

A more detailed explanation of these causal pathways is provided in Box 1 of Krayer von Krauss *et al.* (in preparation).

The experts were asked to comment on whether the diagram mentioned all of the parameters and processes that they thought were key to understanding transcriptional gene silencing, and on whether they thought the diagram contained any superfluous elements.

4.4.2 Level and nature of uncertainty

The second part of the interview focused on the level of uncertainty characterising each of the model locations illustrated in Figure 4.1. In the investigation performed by Krayer von Krauss *et al.* (2004), the scale presented in Figure 3.2 was used to assess the level of uncertainty. One of the conclusions of chapter 3 of this dissertation was that consistency in expert responses could perhaps be increased by using generic descriptive formula to further characterize the terminology used to designate the different levels of uncertainty. On this basis, the scale presented in Figure 3.2 was abandoned in the current investigation, in favour of the pedigree matrix presented in Table VII. The criteria presented in Table VII were developed for the purpose of identifying the level of uncertainty.

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(7) The influence diagram was developed with the help of Prof. Reidunn B. Aalen of the Department of Molecular Biosciences, University of Oslo.

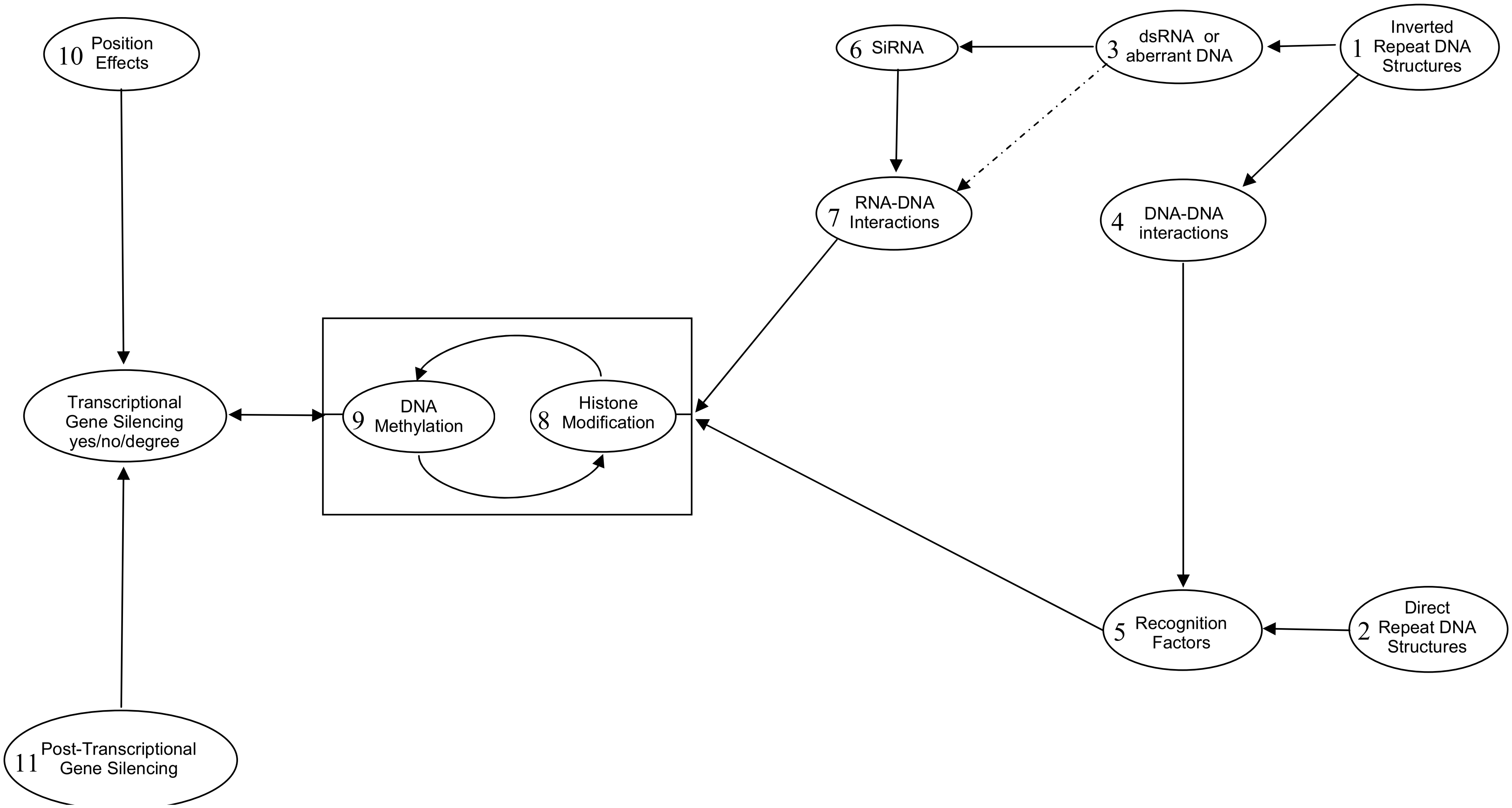

Figure 4.1 Influence diagram illustrating the cause-effect relationships postulated to explain transcriptional transgene silencing (Source: Krayer von Krauss *et al.* (in preparation)).

The criteria were explained to the experts and they were asked to apply them to evaluate each component of Figure 4.1. The level of uncertainty was determined on the basis of the scores obtained, according to the scale presented in columns 1 and 2 of Table VII. In this way, the level of uncertainty was assessed for: i) the structure of the overall model; ii) the structure of each of the three sub-models identified above; and iii) each of the individual components of the model (represented by ellipses in Figure 4.1). Criteria 1, 2 and 3 were applied to evaluate model structure, while the fourth criterion was applied to evaluate individual model components.

Table VII. Criteria for evaluation of the level of uncertainty.

Level of Uncertainty	**Score**	**Evaluation Criteria**			
		1. Level of theoretical understanding	**2. Level of empirical information**	**3. Ability to identify the model structure**	**4. Ability to attribute a value to the model component.**
Determinism	0	Perfect understanding of the system.	Perfect information on the system.	We know exactly what the model structure is.	We know exactly what the value will be.
Statistical Uncertainty	1	We know in great detail how the system works.	We have a great deal of information on the entire system.	We know the range of possible candidate models and their associated probabilities.	We know the range of possible values and their associated probabilities.
Scenario Uncertainty	2	We understand how the main mechanisms of the system work.	We have a considerable amount of information on the system.	We know the range of possible candidate models and we are able to rank them ordinally based on plausibility.	We know the range of possible values and we are able to rank them ordinally based on plausibility.
	3	We only understand parts of the system.	We have some information on the system, but it is limited.	We know the range of possible candidate models, but cannot rank them.	We know the range of possible values, but cannot rank them.
Identified Ignorance	4	We have some clues as to how the system works.	We have only very little information on the system.	We can imagine some candidate models, but it is likely there are other model candidates of which we are unaware.	We can imagine some values, but we don't know the bounds of the range of possible values.
	5	We don't understand the system at all.	We don’t have any information on the system.	We cannot imagine the model structure.	We cannot imagine the values possible.

Experts were then asked to specify whether the uncertainty identified was predominantly due to natural variability in the phenomenon being observed (stochastic uncertainty), or if it was mainly due to limitations in expert knowledge or in the methods available for studying the phenomenon (epistemic uncertainty).

The second part of the interview was ended by asking the experts to assess the sensitivity of the model to errors in the structure of the model, sub-model or model component, using the scale presented in Figure. 4.2. The scale is a slightly modified version of the scale used for this purpose by Krayer von Krauss *et al.* (2004), presented in Figure 3.3. On the scale, a 0 implies that a large change in the element would have only a small effect on the conclusion, a 0.5 implies that a change would have a proportional effect, and a 1 implies that a small change would have a large effect. The scale was explained to the experts and they were asked to assess the sensitivity of the conclusion to changes in each of the key parameters and processes identified in the influence diagram.

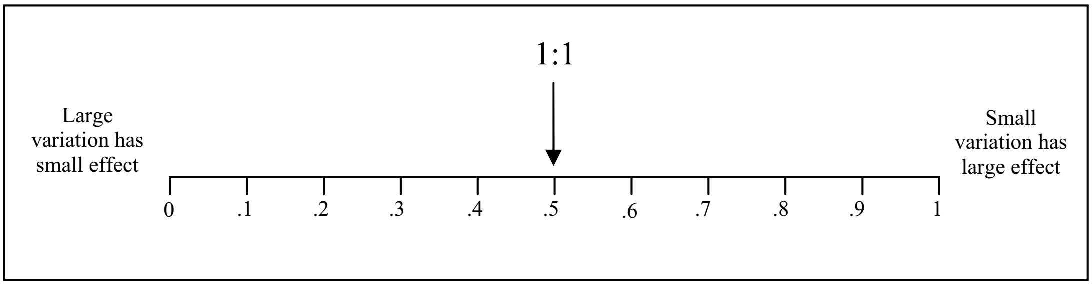

Figure 4.2. Scale used to assess sensitivity (Source: Krayer von Krauss *et al.*, (in preparation)).

4.4.3 Exploring uncertainty

As was explained in section 3.4 of this dissertation, Krayer von Krauss *et al.* (2004) sought to raise awareness of the various sources of uncertainty that can characterise a risk assessment, prior to proceeding to the assessment of the level of uncertainty. In the current investigation, an attempt was made to examine how/if the level of uncertainty identified by the experts would influence the way in which they chose to communicate the uncertainty diagnosed. In view of this, the "awareness raising" exercises had to be omitted from the interview due to time limitations. Following their assessment of the level of uncertainty, the experts were asked to describe the uncertainty identified in terms of a further set of pedigree criteria and a scale of levels of uncertainty. In order to maintain the focus on the use of the W&H framework to diagnose uncertainty, this part of the study conducted by Krayer von Krauss and colleagues will not be elaborated on here. Readers are referred to Krayer von Krauss *et al.,* (in preparation) for details of the approach and the results obtained.

4.4.4 Surprise analysis

The third part of the interview was aimed at fostering a dialogue on issues that may have been left out of the assessment and potential surprises (i.e., context uncertainty). Thus, the experts were asked questions aimed at identifying potential unanticipated or indirect effects associated to gene silencing. The experts were also presented with a scenario intended to help them reflect on potential surprises. The scenario question was as follows:

> "Imagine you have been awarded a sizeable budget to conduct research into transgene silencing and conduct an extensive research program lasting several years. Can you think of a result of this research that would really surprise you?"

4.4.5 Consistency test

Finally, the interviews were ended with a test aimed at verifying how internally consistent the experts were in assessing the uncertainty level and the sensitivity associated with various elements of the influence diagram. Experts were given 100 poker chips and asked to allocate a fixed number of chips to each of the key elements of the influence diagram that they had assessed previously, to indicate how much they would be willing to invest to completely eliminate the uncertainty on that aspect of the influence diagram.

4.5 Results

4.5.1 Model locations and structure

The majority of the experts felt that the influence diagram presented in Figure 4.1 represented the main processes and parameters describing transcriptional gene silencing. However, the interviews did reveal certain areas where the experts disagreed on how some of the components of the diagram were related to one another (i.e., model structure uncertainty). The areas of disagreement concerned the following components of the diagram:

- post-transcriptional gene silencing (ellipse 11);
- position effects (ellipse 10);
- DNA-DNA interactions (ellipse4);
- direct-repeat DNA structures (ellipse 2);
- recognition factors (ellipse 5).
- dsRNA and aberrant RNA (ellipse 3).

One of the experts interviewed felt that the influence of post-transcriptional silencing would be best represented by connecting PTGS (ellipse 11) to dsRNA/aberrant RNA (ellipse 3). The expert explained that siRNA derived from transgenes is incorporated into the cytoplasmic effector complex RISC, which is targeted in sequence-dependent manner to homologous mRNA, resulting in its cleavage. According to the expert, published results indicate that transgenes subjected to posttranscriptional regulation can also be targeted for DNA methylation, suggesting that cytoplasmic and nuclear events may be linked via a common inducer, which is dsRNA (ellipse 3) and/or small RNAs (ellipse 6).

Another expert suggested that the influence of position effects (ellipse 10) and PTGS (ellipse 11) would be best illustrated by connecting these ellipses to the box illustrating histone modifications (ellipse 8) and DNA methylation (ellipse 9), rather than to the TGS ellipse. The expert explained that the possibility that position effects could influence TGS is only based on educated guesses, while there are firmly established findings that position effects play only a minor role. According to the expert, there are firmly established findings that TGS plays a major role in genome defence, e.g. transposon silencing, and it is beyond reasonable doubt that this is correlated to histone modifications (ellipse 8) and DNA methylation (ellipse 9). There is a clear showing that PTGS (ellipse 11) can cause DNA methylation (ellipse 9). Although the potential association between PTGS (ellipse 11) and histone modification (ellipse 8) is only speculative at this point, it seems very likely.

One expert suggested that position effects (ellipse 10) should also be linked to SiRNA (ellipse 6). The expert explained that factors which can contribute to silencing due to position effects are sharp changes of CG content at the insertions sites, presence of short repeats and vicinity to transposable elements. However, positions effects can also include the presence of insertion site-located regulatory elements, which might result in the unintended transcription of parts of the transgene, such as transgene-based promoters. Unintended transcription and thus production of aberrant RNA or antisense RNAs (ellipse 3) might result in the formation of siRNAs (ellipse 6) and silencing via

RNA/DNA interactions (ellipse 7).

Three experts suggested that direct-repeat DNA structures (ellipse 2) could possibly have an influence on dsRNA/aberrant RNAs (ellipse 3). They argued that to date, there is little evidence that direct-repeat DNA structures (ellipse 2) can cause TGS (caused by the structure itself), and therefore the possible links to dsRNA/aberrant RNA (ellipse 3) and recognition factors (ellipse 5) are merely based on educated guesses. One of these three experts indicated that direct-repeat DNA structures (ellipse 2) could also be related to DNA-DNA interactions (ellipse 4), in that it is conceivable that if direct repeat DNA structure influence TGS at all, DNA-DNA interactions occur. The same expert pointed out that the possibility that recognition factors (ellipse 5) play a role in inducing TGS is base on crude speculation. However, if they do play a role, it is likely that they also intervene in the relationship between RNA-DNA interactions (ellipse 7) and the histone modifications (ellipse 8) and DNA methylation (ellipse 9) box.

Two experts suggested that dsRNA and aberrant RNA (ellipse 3) should be represented individually by separate ellipses and that an arrow should emanate from the histone modifications (ellipse 8) and DNA methylation (ellipse 9) box and point to the aberrant RNA ellipse. The aberrant RNA ellipse should then be connected to the dsRNA, which would retain its current position in the diagram (ellipse 3). The experts explained that methylation at asymmetrical sites (CNN, where N is any nucleotide but G) is believed to be maintained by *de novo* methylatransferases DRM1 and DRM2 guided by RNA signals, possibly siRNA (ellipse 6) or long dsRNA (ellipse 3). The RNA signals to maintain complete methylation pattern may be produced by a recently discovered, plant-specific RNA polymerase IV (Pol IV). It is speculated that Pol IV may specifically recognize methylated DNA as a template and transcribe it into aberrant RNA (ellipse 3a). This aberrant RNA might be converted to dsRNA (ellipse 3B) by RNA-dependent RNA polymerase (RDR2). The resulting dsRNA will be cleaved by Dicer (DCL3) into siRNAs that will target cognate DNA for de novo methylation (at both asymmetric and symmetric sites).

4.5.2 Level and nature of uncertainty

Tables VIII and IX present the results of the assessment of the level of uncertainty characterizing the influence diagram (Figure 4.1), based on the pedigree criteria presented in Table VII. Only point estimates were elicited. In Table VIII, the first column lists the sub-models presented in the diagram, and the next four columns show the experts' assessment of how well each of the sub-models scored on the various criteria. Bold numbers are the average of all responses. The fifth column shows the overall strength, a cross row ranking tool, calculated as the average of the scores on that model structure. Bold numbers indicate the average of all the average responses. They are flanked on the left by the average of the lowest scores, and on the right by the average of the highest scores that were given. In Table IX, the first column contains the individual model components assessed, while the next column shows the experts' assessment of how well the model components scored on the criterion used. Here again, bold numbers are the average of all responses. In both Tables, the final column shows the level of uncertainty, determined by comparing the average overall strength to the scale shown in the first two columns of Table VII.

Table VIII. Results of the Evaluation of Level of Uncertainty on Model Structure. (Source: Krayer von Krauss *et al.*, (in preparation)).

Model Structure	**Evaluation Scores Elicited** (0-5)				**Level of Uncertainty**
	Level of theoretical understanding	**Level of empirical information**	**Ability to identify the model structure**	**Overall Strength**	
Overall Model	1, 2, **2.3**, 2.5, 3, 3	1, 2, **2**, 2, 2, 3	1, 1, **1.9**, 2, 2.5, 3	1– **2.1** –3	Scenario Uncertainty
Repeat-induced DNA methylation sub-model	1, **2.4**, 2.5, 2.5, 3, 3	1, 2, 2, **2.2**, 3, 3	2, 2, 2, 2, **2.3**, 3	1,3– **2.3** –3	Scenario Uncertainty
Chromosomal environment of the transgene sub-model	1, 1, **1.8**, 2, 2.5, 2.5	1, 2, 2, **2.3**, 3, 3.5	0, 0.5, **1.8**, 2, 3, 3.5	0.7– **2.0** –3.2	Scenario Uncertainty
PTGS sub-model	0.5, 1, 1.5, **2**, 3, 4	0.5, 1, 1.5, **1.7**, 2.5, 3	1, 1, 1, **2**, 3, 4	0.7– **1.9** –3.7	Scenario Uncertainty

Table IX. Results of the evaluation of level of uncertainty on model components (Source: Krayer von Krauss *et al.* (in preparation)).

Specific Components in Diagram	**Ability to attribute a value to the model component. (0-5)**	**Level of Uncertainty**
1- Inverted Repeat DNA Structures	0, 0.5, 0.5, **1**, 1,3	Statistical Uncertainty
2- Direct Repeat DNA Structures	1, 1.5, **2.2**, 2.5, 3, 3	Scenario Uncertainty
3- dsRNA or aberrant RNA	0, 0, **1**, 1, 1, 3	Statistical Uncertainty
4- DNA-DNA interactions	3, 3, **3.7**, 4, 4, 4.5	Scenario Uncertainty
5- Recognition Factors	3, **3.8**, 4, 4, 4	Identified Ignorance
6- SiRNA	0, 1, 1, 1, **1.4**, 4	Statistical Uncertainty
7- RNA-DNA Interactions	1, 2, 2, **2.2**, 3, 3	Scenario Uncertainty
8- Histone Modification	1, 1, 1, 1, **1.6**, 4	Statistical Uncertainty
9- DNA Methylation	0, 1, **1**, 1, 1, 2	Statistical Uncertainty

As can be seen in Table VIII, the structure of the overall model presented in Figure 4.1, as well as the structure of the sub-models, are characterized by scenario uncertainty. To a certain extent, this concords well with the fact that, as was illustrated by the disagreement revealed in the assessment of the completeness of the influence diagram, there are competing scientific interpretations of the mechanisms leading to transcriptional gene silencing. Given the comment made by one expert in the first part of the interview, to the effect that the possibility that position effects could influence TGS is only based on educated guesses, one may have expected that the model structure of the chromosomal environment sub-model would be judged more uncertain than other sub-models. This is not reflected in the results. It is however interesting to note that there seems to be more disagreement amongst experts regarding the structure of the chromosome environment and PTGS sub-models, than there is in the case of the repeat-induced DNA methylation sub-model and the overall model.

The results presented in Table IX indicate that two model components, DNA-DNA interactions and recognition factors, are characterized by a high level of uncertainty. This concords with the comments made by some of the experts during the assessment of the completeness of the influence diagram.

Figure 4.4 shows the relative level of uncertainty, the sensitivity of the model (Figure 4.1), as well as the "influence" of the uncertainty identified. The relative level of uncertainty was calculated by dividing the overall strength scores presented in Table VIII, and the min, max and mean score presented in Table IX, by the maximum achievable score (i.e., divided by 5). The influence of the uncertainty was calculated by taking the square root of the product of the relative level of uncertainty and the sensitivity ($I = (L_{/5} \times S)^{1/2}$). In the Figure, solid symbols denote mean values. They are bounded on the left by the lowest, and on the right by the highest, values.

Table X presents the responses given by each expert on the questions pertaining to the level of uncertainty, with the mean and standard deviation of these responses. As can be seen in the Table, all of the experts interviewed varied their responses across the spectrum of possible answers, but there seems to be a tendency for some experts to anchor their response on certain values. Furthermore, expert 5 generally seemed to judge the level of uncertainty to be notably higher than what his colleagues judged it to be, which could be an indication of difference perspectives on uncertainty.

Table X Responses by individual experts on level of uncertainty.

Expert	Responses on level of uncertainty	Mean; Standard Deviation
Expert 1	0.5, 1, 1, 1, 1, 2, 2.5, 3	1.5; 0.8
Expert 2	0, 0, 1, 1, 1, 1, 1, 4, 4	1.4; 1.4
Expert 3	0, 0, 1, 2, 2, 3, 3, 4	1.8; 1.3
Expert 4	0.5, 1, 1, 1, 1, 1.5, 3, 3, 4.5	1.8; 1.3
Expert 5	0, 3, 3, 3, 3, 4, 4, 4, 4	3.6; 1.2

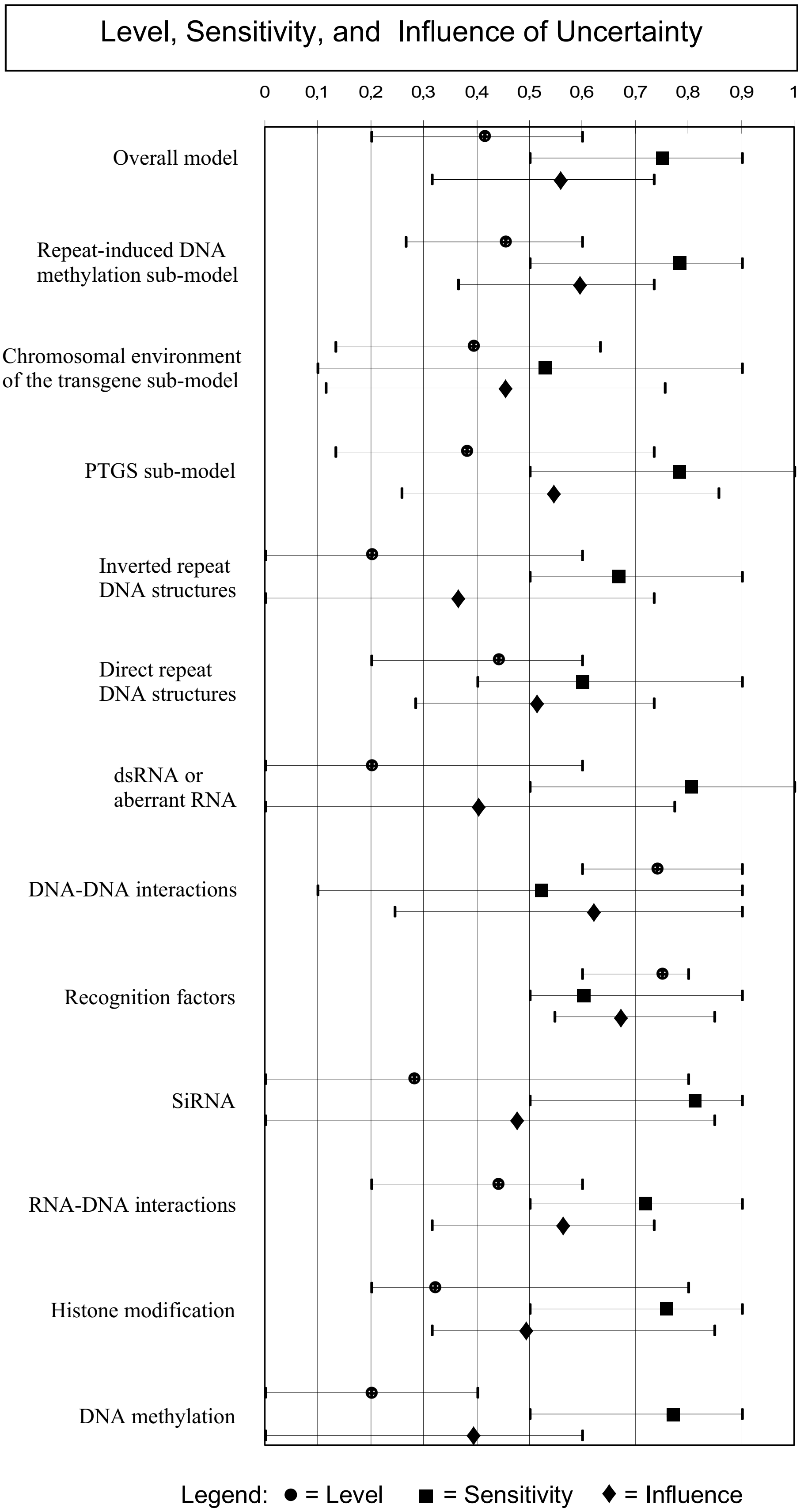

Figure 4.4 Results of assessment of the relative level, the sensitivity, and the influence of uncertainty ($I = (L_{/5} \times S)^{1/2}$). Only point estimates were elicited. Solid symbols denote mean values. They are bounded on the left by the lowest, and on the right by the highest, values (Source: Krayer von Krauss *et al.*, (in preparation)).

Table XI presents the results of the assessment of the nature of uncertainty. Here, stochastic uncertainty is uncertainty due to the inherent variability of the phenomena under consideration, and epistemic uncertainty is due to limitations in our knowledge. The values shown in the Table indicate the number of experts who thought that the uncertainty they had identified was predominantly due to the type of uncertainty in question (stochastic or epistemic uncertainty). The results suggest that it could be possible to reduce uncertainty by conducting additional research into the model components Inverted repeat DNA structures, Direct Repeat DNA structures, DNA-DNA interactions, and Recognition factors. Conversely, as the uncertainty characterizing the model component dsRNA or aberrant RNA is dominated by natural variability, it is unlikely that it can be reduced much further by conducting additional research. Not all rows sum to 5 due to the fact that one expert preferred not to express himself on Recognition factors, considering this outside of his field of expertise.

Table XI. Results of assessment of nature of uncertainty.
(Source: Krayer von Krauss *et al*. (in preparation))

Element of influence diagram	Nature of Uncertainty	
	Stochastic	Epistemic
Overall model	2	3
Repeat-induced DNA Methylation sub-model	2	3
Chromosomal environment Of the transgene sub-model	2	3
PTGS sub-model	2	3
Inverted repeat DNA structures	1	4
Direct Repeat DNA structures	1	4
dsRNA or aberrant RNA	4	1
DNA-DNA interactions	1	4
Recognition factors	0	4
SiRNA	3	2
RNA-DNA interactions	2	3
Histone modification	3	2
DNA methylation	3	2

4.5.3 Surprise analysis

Many of the experts interviewed indicated that scientists' knowledge of the mechanisms leading to transcriptional gene silencing is rapidly evolving and that they would therefore expect surprise discoveries to take place in the future.

One expert mentioned that he would be surprised to observe a situation where all of the RNA components necessary for repeat-induced DNA methylation to take place were present, but silencing does not occur, possibly indicating that environmental conditions exercise an influence on this pathway.

The NGO representatives put forth the following scenario as a possible biosafety risk related to gene silencing:

> "In order to engineer resistance to a target virus, a viral gene can be inserted into a plant. If this gene becomes silenced the plant will be

> resistant to the virus. When a virus enters the plant this silencing effect transfers to the virus- thus preventing infection. In this situation gene silencing is used deliberately to induce virus resistance, even though not all transformants carrying the gene will be resistant to the virus.
>
> Safety tests on the crop are done on an uninfected plant in which silencing is active, thus little or no transgenic viral protein is being produced by the plant. If transgene silencing were unstable, then the viral gene would be expressed at a higher (probably much higher) level and one could argue that safety tests (e.g. compositional analysis) would no longer be valid.
>
> Secondly, elevated expression of a virus gene may itself constitute a health hazard. Viral genes inserted into plants are usually considered safe because the protein is expressed at a low level. Low level expression of the transgene protein would no longer be a property of the crop if silencing was instable /inactivated."

While the focus of this study has been on the scenario whereby a transgene intended to be expressed is accidentally/unexplainably silenced, the above scenario represents the inverse situation, whereby the intention is that the transgene be silenced, but this accidentally/unexplainably fails.

Two experts were questioned on the plausibility of the above scenario, and on whether it could be argued that, if scientific knowledge is limited to the extent that silencing cannot always be explained, then, conversely, it was not possible to predict the failure of intentional silencing in all cases.

The experts judged the scenario to be plausible. Due to the many biotic and abiotic factors that can lead to suppression of silencing, it is not possible to predict whether silencing will be stable in all cases. However, the experts questioned the extent to which the expression of high levels of viral proteins could be considered as a health risk. They felt that if so, many of the conventional fruits and vegetables sold in supermarkets would have to be considered hazardous as they likely contain high levels of different viruses.

4.5.4 Consistency

Figure 4.5 illustrates the results of the consistency tests, in the form of an index of uncertainty influence versus the willingness to pay to eliminate uncertainty. Willingness to pay is based on the number of poker chips the experts were willing to "invest" into research on a particular component of the influence diagram in order to completely eliminate the uncertainty on that component.

One hundred chips were given to the experts to apportion among research needs. A consistent expert would be expected to allot more chips to components for which the influence of uncertainty is large (i.e., high levels of uncertainty *and* sensitivity), *and* for which the uncertainty is predominantly of an epistemic nature. In Figure 4.5, the dotted trendline indicates the trend in how experts invested their chips on model components they thought were dominated by epistemic uncertainty. The solid trendline indicates the trend in how experts invested their chips on model components they thought were dominated by stochastic uncertainty. As can be seen in the Figure, apart from the trendline indicating that experts would be willing to invest increasing amounts of resources as the influence of epistemic uncertainty increases, consistency was not a prominent feature of the responses given by the experts. Thus, the use of generic descriptive formula to further characterize the terminology used to designate the different levels of uncertainty did not have a significant impact on the consistency with witch experts applied the various concepts put forth in Walker *et al.*, (2003).

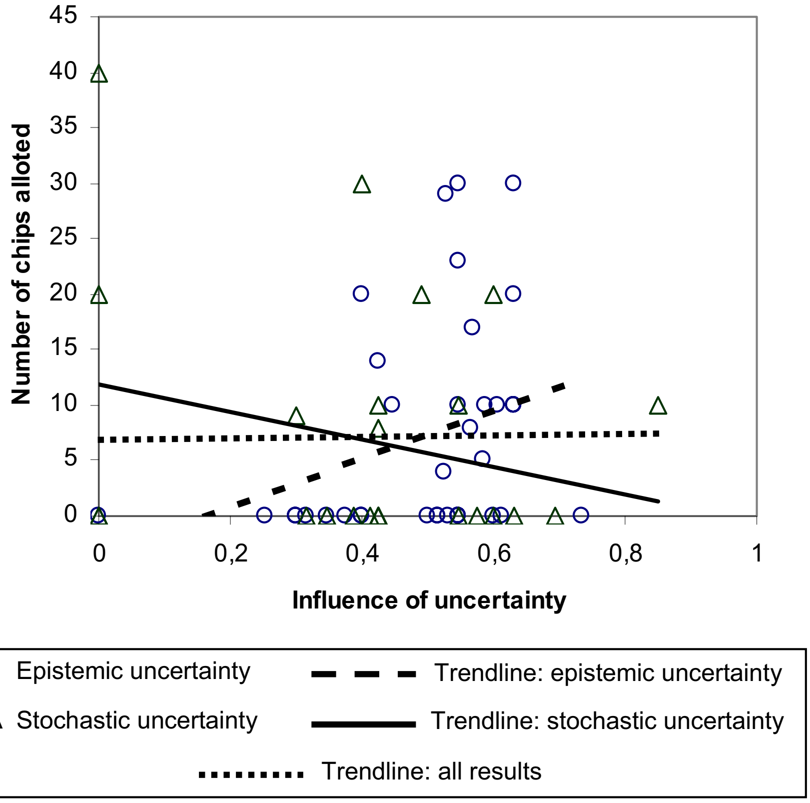

Figure 4.5 Consistency index between the influence of uncertainty and the willingness to pay to eliminate uncertainty (Source: Krayer von Krauss *et al.* (in preparation)).

4.6 Discussion

Because it could not be expected that the experts involved in this study were familiar with the concepts put forth in the Walker and Harremoës conceptual framework, efforts were required to communicate the framework without intimidating or confusing the experts, while still obtaining their knowledge of the location, level and nature of uncertainty. For this reason, this study used expert elicitation as a method to coach experts through the application of the Walker and Harremoës conceptual framework. Ultimately however, it is envisioned that experts providing scientific advice to inform policy decisions would receive training with the conceptual framework, such that they could use it as a reflexive tool to diagnose and communicate the uncertainty characterizing their assessments. This is what is currently taking place at the Netherlands Environmental Assessment Agency (Janssen *et al.*, 2005).

The relative lack of consistency in the responses given by the experts (see Figure 4.5), could indicate that the experts did not necessarily fully grasp the concepts put forth in the questions they were asked, notwithstanding the fact that generic descriptive formula were used to further characterize the terminology. However, it could also indicate that subjective factors had an influence on how the experts responded to the questions. It cannot be ruled out that ambiguity in the questions may have lead to different interpretations, or that personal biases may have had an influence.

As has been observed in other expert elicitation studies (Krayer von Krauss *et al.*, 2004; Morgan *et al.*, 2001; Morgan and Keith, 1995; Stirling and Mayer, 2001), the quantitative results of the elicitation display a much richer diversity of expert opinion than the consensus documents typically published by regulatory authorities. In many cases, these documents are written in such a way that they mask the diversity of expert opinions. Moreover, because this form of "one-way" communication (i.e., where the intended audience does not participate) is necessarily constrained by the limited spectrum of symbolic resources available for written communication, it often masks the diversity of perceptions associated with words such as "likely", "uncertainty" and "ignorance". Thus, while the impression of a consensus may be conveyed, reality is such that each of the experts contributing to a given assessment, and each of the policy makers and stakeholders reading it, may have a different interpretation of the message communicated in the document. This has been demonstrated well by empirical research into risk communication and experience in practice (Patt and Schrag, 2003; Patt and Dessai, 2005; Morgan, 1998; Wallsten *et al.*, 1986).

The ambiguity of the results generated by an uncertainty analysis such as the one performed in this study may lead some to question the usefulness of investing the efforts required to perform the analysis. However, it is important to recall that the goal of performing such analyses is to provide substance to a deliberative decision making process, in view of fostering reflexivity. Within a deliberative policy making process, the interpretive flexibility offered by qualitative descriptors of uncertainty is not necessarily a negative thing. Although the use of relative terminology such as "considerable", "good/bad", "likely", "uncertain" and "ignorance" may be a source of ambiguity, it also forces stakeholders to deliberate on the meaning of these terms, and can thereby help bridge the diversity of positions and framings held by the various actors involved (Shackley and Wynne, 1997; Star and Griesemer, 1989; Eisenberg, 1984).

4.7 Conclusion

The results of this study reveal that some aspects of the scientific knowledge of transcriptional gene silencing are characterized by high levels of uncertainty. The results show that their are competing hypotheses regarding some of the cause-effect relationships leading to the phenomenon (model structure uncertainty). Furthermore, the model components "DNA-DNA interactions" and "Recognition factors" were characterized by high levels of uncertainty. As a large majority of the experts interviewed agreed that the uncertainty characterising these model components was predominantly epistemic in nature, it would seem appropriate to conduct further research on these components.

There seemed to be little consistency in the responses provided by the experts. Nonetheless, the study was successful in highlighting several sources of uncertainty at levels above and beyond the statistical uncertainty commonly reported on, as well as in making explicit a diversity of expert opinions on the uncertainty characterising transgene silencing.

5 Overall discussion & conclusion

The goal of this chapter is to offer reflections on the experiences gained in the process of applying the W&H framework. It view of doing so, it is useful to begin by briefly recalling the premise upon which this project is based, as was outlined in chapter 1. The precautionary paradigm implies increased democratisation, adaptability and reflexivity in public decision making. Deliberation is used as a means of confronting different perspectives to oneanother, thereby highlighting disagreement and increasing reflexivity. Important topics of deliberation will include the quality of the information upon which a decision needs to be made, the precautionary measures warranted and the general desirability of technological innovations.

The precautionary paradigm has profound implications for the role of experts in the decision-making process. Rather than providing an optimal technical answer, the role of experts is to participate in the collective effort of producing, evaluating and applying knowledge, considering the interests at stake, and making a necessarily provisional decision. Experts are now expected to reflect publicly on the quality of their knowledge, reveal their uncertainties and open up to questioning and confrontation by other members of the policy community. New institutional arrangements and methodologies are required to help experts assume their changed roles under the precautionary paradigm. An area in which there is an obvious need for methodological innovation is in uncertainty assessment. Too often, the notion of uncertainty has been over simplified, if not neglected all together. What has commonly been referred to under the umbrella term “uncertainty” actually hides important technical distinctions. The scientists and engineers performing regulatory assessments must emancipate themselves from the widespread statistical or probabilistic understanding of uncertainty, to recognize the full spectrum of the uncertainties characteristic of policy relevant science. Only communicating statistical uncertainty, or communicating scenario uncertainty and ignorance in statistical terms, risks conveying a pretence of high certainty, when this is not actually the case.

Thus, there is a requirement for methods through which experts can systematically diagnose uncertainty at levels over and above statistical uncertainty, and explicitly communicate these uncertainties to the other actors in the policy community. In the process of doing so, disagreements, and thereby the different perspectives on uncertainty, will be made more obvious. Information about uncertainty, and the different perspectives on this uncertainty, enrich the basis for deliberations on the quality of information.

In view of the above, this project set off with the objective of developing the best possible method for diagnosing and describing the uncertainty characterising regulatory assessments. The method developed was to be consistent with the body of literature on uncertainty, integrate the different conceptual approaches described in this body of literature, and thereby address levels of uncertainty above and beyond the statistical uncertainty commonly described by engineers and scientists. The pursuit of this objective lead to the development of the W&H conceptual framework for uncertainty analysis, in which uncertainty is described as a three dimensional concept, including the level, location and nature of uncertainty.

The initial perspective of the author of this dissertation was that if defined well enough, uncertainty at levels beyond statistical uncertainty could be identified and described in a unique, absolute fashion, similar to the way in which statistical uncertainty is described. The different dimensions of uncertainty having been defined by Walker *et al.*, (2003), the author set out to test the W&H framework. The approach taken to test the framework was to develop an elicitation protocole in which the concepts put forth in the W&H framework were reflected, and to use the protocole to elicit experts on the uncertainty characterising the two case studies reported on in chapters 3 and 4 of this dissertation.

In the first of these two empirical studies, the expert elicitations revealed three issues of potential concern that were left outside the scope of the risk assessment of herbicide tolerant oilseed crops. The results also drew attention to two areas within the risk assessment where knowledge was completely lacking. A striking feature of the results of the first study is the large diversity in the expert opinions elicited. As is manifested in Figure 3.4, the elicitations highlighted considerable disagreement amongst experts regarding the level of uncertainty. Figure 3.5 illustrates that considered individually, each of the experts varied relatively little in their judgements of the level of uncertainty. This suggests that the diversity of opinion observed could reflect the presence of different perspectives on uncertainty within the groups of experts that took part in the study. However, these results could be confounded by the fact that the experts were anchoring there responses around a given value. Also, the consistency test performed indicated that the experts interviewed were not using the concepts put forth in the W&H framework consistently (see Figure 3.6). This could indicate that, although care was taken to explain the level and nature dimensions of uncertainty, the novelty of the concepts involved, or ambiguity in the formulation of the questions, may have lead some experts to interpret the questions differently, or let personal biases influence their responses.

The diversity and ambiguity of the results obtained in the first study lead to a change in the approach used in the second study. The strictly numerical scale used to determine the level of uncertainty in the first study (see Figure 3.2) was abandoned. Instead, a set of pedigree criteria containing qualitative descriptors of the different levels of uncertainty was developed (see Table VII). The second study successfully revealed that there are competing hypotheses regarding some of the cause effect relationships leading to transgene silencing, and that the experts elicited thought that certain components of the system model were characterized by high levels of scenario uncertainty and identified ignorance. As can be seen in Figure 4.5, the results of the second study indicated a slight improvement in the consistency with which experts responded, which may be (partially) attributable to the use of the pedigree criteria to assess the level of uncertainty. By and large however, notwithstanding the fact that generic descriptive formula were used to further characterize the terminology, consistency was still not a major feature of the responses elicited. As was the case in the first case study, the results of the second elicitation study still display a considerable diversity of expert opinion (e.g., see Tables VIII and IX, and Figure 4.4). Here again it is difficult to determine whether the diversity of the responses given reflects true disagreement amongst the experts, diverging interpretations of the questions asked to them, or both.

The ambiguity of the results generated in the two case studies performed may lead some to question the usefulness of investing the efforts required to perform the analysis. However, it is important to recall that an important goal of such analyses is to provide substance to a deliberative decision making process, in view of fostering reflexivity. Within a deliberative policy making process, the interpretive flexibility offered by qualitative descriptors of uncertainty is not necessarily a negative thing. Although the use of relative terminology such as "considerable", "good/bad", "likely", "uncertain" and "ignorance" may be a source of ambiguity, it also forces stakeholders to deliberate on the meaning of these terms, and can thereby help bridge the diversity of positions and framings held by the various actors involved (Shackley and Wynne, 1997; Star and Griesemer, 1989; Eisenberg, 1984).

The diversity of the responses provided by the experts in the two empirical studies conducted, as well as experience gained in discussing the W&H framework in various academic fora, suggest that there can be no absolute description of uncertainty. As was illustrated by Rayner (2004), a variety of psychological and social factors will contribute to the way in which uncertainty is experienced, just as is the case with risk. Any characterisation of uncertainty will itself be uncertain (O'Riordan and McMichael, 2002). While the concepts put forth in the W&H framework seemed intuitive to it's authors, this has not always proven to be the case in practice, and different, equally legitimate, conceptual arrangements could undoubtebly be devised to describe uncertainty.

In view of the above, the initial perspective of the author of this dissertation, that by defining the different levels of uncertainty well enough, it would be possible to diagnose their presence in a case study and describe them using a conventional vocabulary that is universally understood, seems a rather naive remnent of the modern, positivistic paradigm. There will always be a plurality of perspectives on uncertainty, and uncertainty assessment can only aspire to make this transparent. Thus, the relative value of the approach presented in this dissertation should be evaluated in terms of the extent to which it helped make a broad spectrum of uncertainties, and the plurality of perspectives on uncertainty, transparent.

In both of the case studies presented in this dissertation, experts were successfully engaged in a dialogue that stimulated them to systematically reflect upon a broad spectrum of uncertainties. In both of the cases studied, the experts identified levels of uncertainty above and beyond statistical uncertainty, and a large diversity of expert opinion was revealed. On this basis, it seems reasonable to conclude that the approach applied here contributed to making a broad spectrum of uncertainties, as well as the plurality of perspectives on uncertainty, transparent.

An avenue of future study would be to experiment with the W&H framework in a deliberative context. This would require adapting the approach used in the current study to elicit individual experts, such that it could be used with focus groups. The composition of focus groups could be representative of the variety of stakeholders in the regulatory debate. In addition to the concepts put forth in the W&H framework, the members of a focus group would be stimulated to reflect on the opinions of their colleagues. A heightened level of reflection could therefore be hoped for, provided that care was taken to avoid some of the pitfalls associated with group dynamics (e.g. the influence of pride and egos, hierarchal relationships based on status, etc...).

While it would seem beyond doubt that the applications of the W&H framework illustrated here generated reflection on behalf of the experts involved, it is difficult to gauge the extent to which the approach would be succesful in fostering reflexivity in decision making. In view of doing so, it would be useful to identify parameters through which reflexivity can be gauged. An example of one such parameter could be learning or adaptation. In other words, by observing the extent to which the insight gained by applying the W&H framework subsequently influences how decisions are made, it might be possible to evaluate the extent to which the approach is successful in fostering reflexivity. In an experimental context, this could be accomplished by simulating a decision making situation, by asking the participants in an eventual study to make a decision in view of the information on uncertainty they were presented. Another approach would be to study a case in practice in which uncertainty information was considered in the process leading up to a decision.

There is no reason to believe that the shift from the modern to the precautionary paradigm will be easy. Professional cultures are not easily transformed, especially in the situations of high stakes and disputed values that characterize many regulatory decision-making processes. It is very likely that the shift, where it occurs, will proceed gradually and with difficulty as the different actors of the policy community increase their willingness to experiment with new modes of interaction and decision making.

The approach presented in this dissertation is a methodological contribution aimed at facilitating the transition towards the precautionary paradigm. Applied regularly, uncertainty analyses such as those presented in this dissertation could contribute to the systematic characterisation and communication of forms of uncertainty that are rarely made explicit in policy sciences. As such, they could make an important contribution to the basis for deliberations on the quality of the information underpinning policy decisions, the extent of the precautionary measures warranted, and the way in which monitoring resources should be allocated. Ultimately, this could lead to increased reflexivity in regulatory decision making.

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Defining uncertainty. A conceptual basis for uncertainty management in model-based decision support.

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Appendix 1

Elicitation of expert judgments of uncertainty in the risk assessment of herbicide tolerant oilseed crops

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Appendix 2

Uncertainty and Precaution in Environmental Management.

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Appendix 3

Using the W&H integrated uncertainty analysis framework with non-initiated experts

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Appendix 4

Diagnosing & Communicating Scientific Uncertainty: a Case Study of Transgene Silencing.

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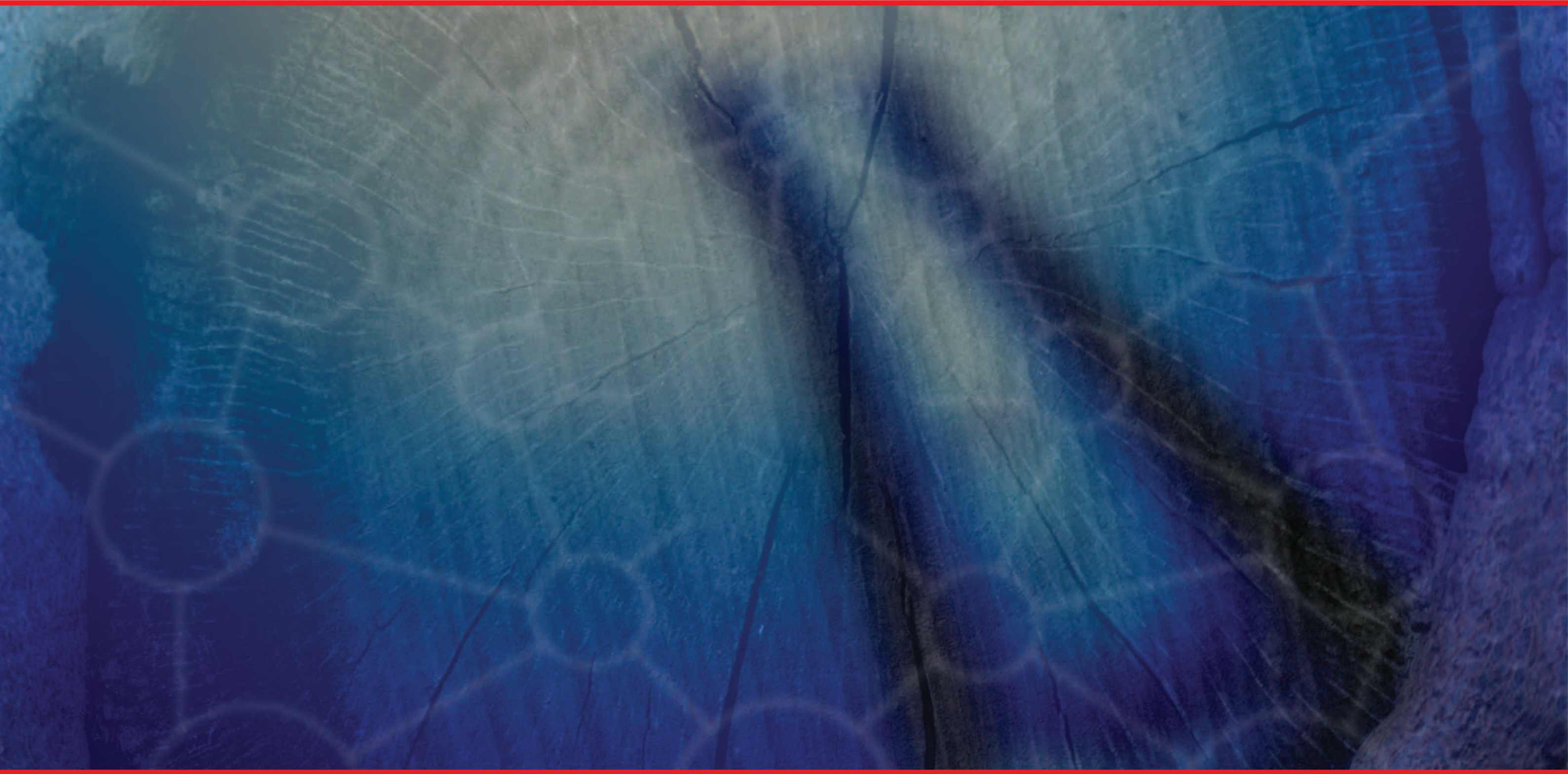
Appendix 5



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