REGULATORY SCIENCE AND UNCERTAINTY IN THE RISK ASSESSMENT OF PESTICIDE RESIDUES

REBECCA E. DIGGLE, BSc, MA

Thesis submitted to the University of Nottingham

for the degree of Doctor of Philosophy

May 2010

Abstract

In this thesis I examine how the scientific advisory system in England and Wales has responded to concerns about the risks of pesticide residues in food and demands for wider engagement in the formulation of advice. Specifically, I explore how the Advisory Committee on Pesticides (ACP) frames scientific uncertainties in risk assessment, and why some bodies outside and within government are critical of the ACP's approach that is centred in the conventional single-chemical, high-dose-response paradigm of toxicology. Although some of these challenges date back to the early history of pesticide regulation in England and Wales, the emergence of scientific research employing different methods to assess the effects of chemical mixtures and chronic low-level exposure has stimulated new concerns about the risks posed by pesticide residues for human health.

Using semi-structured interviews and documentary analysis, a key finding is that concerns about low-level exposure to chemical mixtures have been persistently bracketed in official advice as insufficient for changing current advice and regulation. Drawing from literature in science and technology studies, I account for this finding in three ways. First, it is perceived that change is unnecessary since established methods of pesticide risk assessment represent an exemplar for other domains. Secondly, evidence selection by the ACP and related committees is shaped by regulatory guidelines which aim to provide standardisation and quality assurance, but also constrain judgements about which risk assessment studies are considered admissible. Thirdly, fundamentally different notions are at play

in terms of what constitutes legitimate expertise and who should embody it, leading to tensions within government as well as between the ACP and NGOs. These limit the impact of post-BSE attempts to make the role of scientific advice in policy-making more participatory and 'evidence-based', and the capacity to introduce new paradigms of chemical risk assessment in the pesticide advisory process.

Acknowledgements

This PhD is for my husband Adam, who has been lovely and extraordinarily patient with me over the last year.

I would like to thank my supervisors: Dr Kate Millar, Professor Paul Nathanail and Dr Sujatha Raman for all the support they have provided me. In particular, I express my gratitude to Sujatha, whose kindness and gentle chivvying helped me keep going during those times I would rather have stopped.

I would like to thank Professor Robert Dingwall for his support during Dr Raman's leave and Professor Anne Murcott for providing a friendly ear and the opportunity to discuss my work outside of the supervisory process. Not least, I express my appreciation to Mrs Gill Farmer, who could be relied upon to sort out any problem big or small, and sometimes just simply listen.

I would also like to express my gratitude to those I interviewed and those people, too numerous to name, that assisted me through the course of this research.

Lastly, I would like to thank my parents for their encouragement during my time at university.

Table of Contents

Chapter 1: Introduction

1.1 Introduction

This thesis considers how uncertainty is addressed in the risk assessment and advisory process in England and Wales for pesticides, specifically potential risks associated with the consumption of pesticide residues in food. Recently, previous assumptions made by both scientists and regulators that exposure to low-levels of chemical mixtures are unproblematic to human health are being challenged, with scientific research beginning to suggest that interactions at low-levels may cause toxicological effects (Colborn *et al.*, 1993; Henschler *et al.*, 1996; Rajapakse *et al.*, 2002; Royal Commission on Environmental Pollution, 2003; Sheehan, 2006; Christiansen *et al.*, 2009). Consumer advice from the Food Standards Agency regarding pesticide residues is clear in stating that the current assessment system is adequate in protecting the public's health and that: *"the risk to people's health from mixtures of residues is likely to be small"* (Food Standards Agency, 2004b). However, such advice has been challenged as the concern surrounding chronic exposure to low-levels and exposure to mixtures or 'cocktails' of chemicals, and pesticides in particular, has grown among British NGOs (Friends of the Earth, 2004b; Pesticide Action Network, 2004; Women's Environmental Network, 2004; WWF-UK, 2004), as well as policy-makers at the European level (European Commission, 2004a). This thesis will explore how the risk assessment system, centred around the Advisory Committee for Pesticides (ACP), has dealt with these challenges.

As in other UK scientific advisory areas, the pesticide advisory system can be characterised as being in a state of flux, a system that is still responding to changes instigated in the mid-90s by the most prominent of all UK food safety crises involving the risk of transmission of bovine spongiform encephalopathy (BSE) to humans. The controversy surrounding BSE became a catalyst for change in the formal organisation of UK scientific advice, as the traditional closed style of advisory decision-making that had previously been praised for its capacity to negotiate mandates for environmental protection in some areas (Jasanoff, 1986; Vogel, 1986; Jasanoff, 1990), was seriously questioned by both the public and the then newly appointed Labour Government. In a widely cited report, the House of Lords Select Committee on Science and Technology (2000) spoke of a crisis in the relationship between science and society, while the Royal Commission on Environmental Pollution (1998) called for greater awareness of the role of value judgements in the setting of environmental standards. The former Chief Scientific Adviser, Sir Robert May introduced guidelines for greater transparency in the scientific advisory process (Office of Science and Technology, 1997) and the UK Government began to advocate a widening of participation to include not only alternative sources of scientific and technical expertise but also lay representatives (The Strategy Unit, 2002). Government departments were also given guidelines to follow the tenets of ‘evidence-based policy’.

Thus, in addition to the long standing demands of both the agrochemical industry and farming unions to relax pesticide related regulations, and the requirement to comply with international standards, such as those imposed by the World Trade Organisation and European harmonisation,

there are now two additional and distinct pressures on pesticide risk assessment: first from other scientific, public and governmental concerns surrounding the need to consider realistic scenarios of low-level chemical exposure to multiple pesticide residues and second, from the new demands for wider participation in the risk assessment process. This thesis therefore seeks to explore how the scientific advisory system in England and Wales has responded to concerns about the risks of pesticide residues in food and demands for wider engagement in the formulation of advice through addressing the following research aim:

How are the twin challenges posed by changes in the organisation of the British advisory system and by emerging scientific uncertainties in chemical risk assessment managed in the case of risk assessment of pesticide residues in food, and to what effect?

In order to elaborate the context for these challenges, in the next part of this chapter (1.21) I provide an overview of the chemical risk assessment process, moving on in Section 1.22 to discuss the challenges posed in the assessment and management of chemical mixtures. In Section 1.23 I consider why pesticide residues are a good case study to explore how these challenges have been managed in practice.

In Section 1.3 I discuss the wider changes to the UK scientific advisory system and how this may affect pesticide assessment practices. Lastly, in Sections 1.4 and 1.5 I present my research questions and provide an overview of the layout and chapter structure of the thesis.

1.2 Research rationale

Humans and the environment are continuously exposed to a wide range of industrial chemicals. While there are over one hundred thousand chemicals registered on the European market, fewer than five percent of these have been subject to "positive approval" for use in specific products (Defra, 2005). The remaining ninety-five percent are allowed to be freely used unless they are specifically regulated on the basis of toxicological evidence that identifies them as toxic, carcinogenic or mutagenic. As a result, many of these chemicals have either never been tested or been subject to only limited scientific investigation; their long-term effects on human health and the environment is therefore unclear and at present difficult to determine.

Currently, European regulatory guideline values for many non-carcinogenic[1] chemicals – including pesticides - are derived from data obtained through toxicological assessment that is grounded in the concept of dose response modelling. The Food Standards Agency (FSA) states that these studies are "based on internationally accepted guidelines" and that they "establish what scientists agree is an acceptable dose to humans, usually based on a 'no observed adverse effect level' (NOAEL) in animals"

[1] Chemicals are typically assessed differently depending on their capacity to induce cancer, with non-carcinogenic chemicals typically working within a scientific model that is grounded in the concept of threshold doses, where exposure to levels of chemicals below the threshold is seen as acceptable. For those chemicals that are recognised as carcinogenic, and more specifically as genotoxic carcinogens, all exposure is seen as potentially risky, i.e., there is no safe dose. This is discussed further in Chapter Three.

(Food Standards Agency, 2004b). Typically, chemicals are assessed in isolation with tests focusing on a "single media, single source and single toxic endpoint" (IPCS, 2001). Although this tightly bounded approach to assessment may from an outsider's perspective be viewed as somewhat reductive in its scope, the process of assessing risk from single chemical substances is historically well established and believed among the regulatory and toxicology community to be generally reliable and robust; other chemical related risks such as those created from exposure to chemical mixtures are in contrast recognised by these communities as less well researched, often being characterised by a high degree of uncertainty (Colborn *et al.*, 1993; van Zorge, 1996; De Rosa *et al.*, 1998; Royal Commission on Environmental Pollution, 2003; Weinhold, 2003; Wharfe *et al.*, 2004). This has led many groups including scientists, campaigners, policy-makers and advisory bodies to call for greater use of integrated approaches that consider realistic multi-chemical, multi-route exposure scenarios (IPCS, 2001; Pesticide Action Network, 2002; Friends of the Earth, 2004b).

1.21 Chemical risk assessment framework

As the terms risk and risk assessment are used in different ways, I will first clarify the official meaning of "risk assessment" as it is used in the scientific literature. The conventional risk assessment paradigm consists of four parts - hazard identification, hazard characterisation, exposure assessment and risk characterisation – where Defra describe a hazard as: "any situation that in particular circumstances could lead to harm", and risks as "a combination of the probability of occurrence of a defined

hazard and magnitude of the consequences of the occurrence" (Defra, 2000). A schematic illustration taken from Defra's Guidelines for Environmental Risk Assessment and Management is shown in Figure One.

Figure 1: A Framework for Risk Assessment and Management (Defra, 2000)

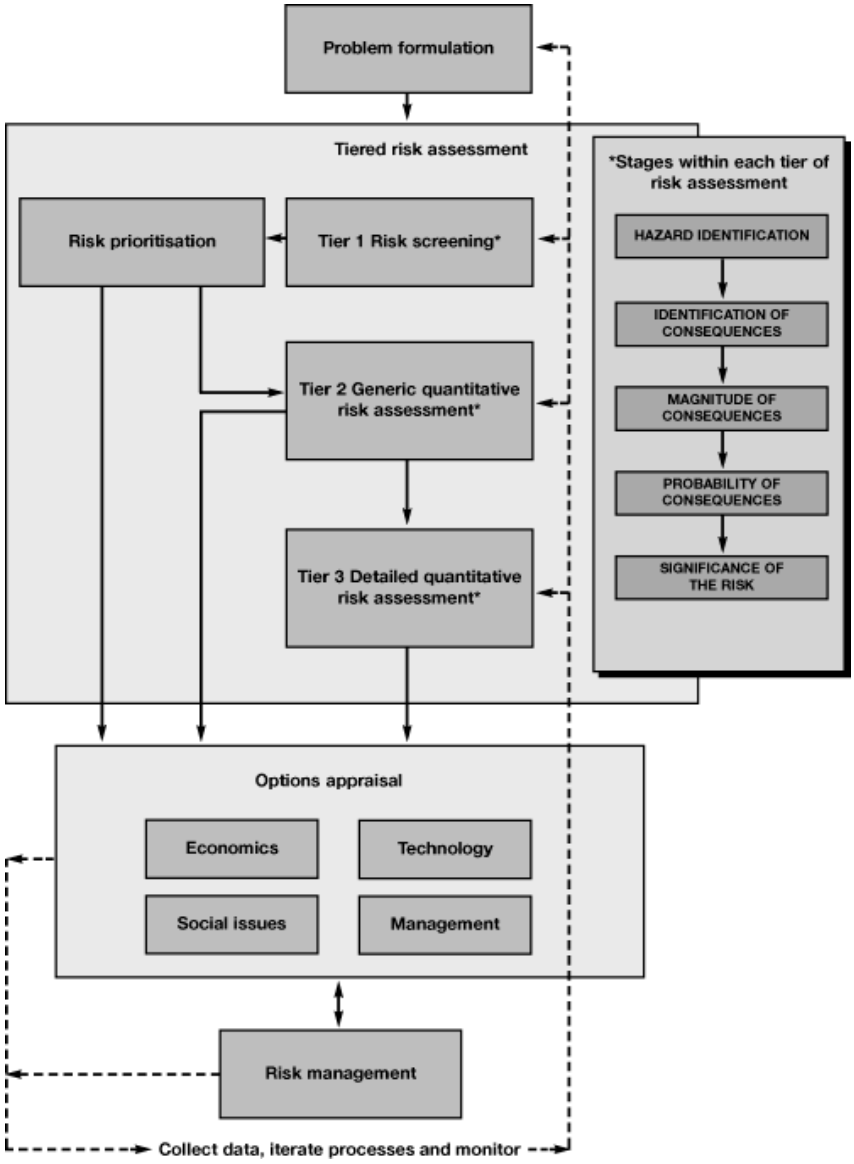

Figure one highlights the iterative nature of the risk assessment process and suggests that risk assessment and risk management are seen by Defra as separate activities. Throughout the chemical risk assessment process a variety of experimental activities will occur. During stage one - hazard identification - the inherent capacity of a chemical to cause one or more adverse effects will be identified. This identification is followed by a process of hazard characterisation. During this stage there will be a semi-quantitative evaluation of the chemical in question that will include factors such as dose response and toxic potency. The toxicity of a chemical is usually determined using a combination of the following three methods; epidemiology, *in vivo* and *in vitro* methods.

The third stage - exposure assessment - may be described as the semi-quantitative evaluation of the likely exposure of man and/or the environment to a chemical (Anon, 2002 b). It is used to qualify the level of chemicals to which humans and the environment are exposed with regards to the magnitude, duration and frequency (Risk Assessment and Toxicology Steering Committee, 1999). Assessment of exposure is an important part of the risk assessment process as it is only through exposure that a chemical changes from being defined as hazardous into a risk.

The final stage of the risk assessment process is that of risk characterisation. As risk characterisation is based on the information that has been obtained during the process of risk assessment, it is crucial that all relevant information regarding the possibilities of toxic effect and route of exposure be considered and the right questions asked.

While many scientists and regulators would argue that the risk assessment process as shown in Figure One is robust enough to cope with new findings and new methodological developments, it is also increasingly acknowledged within these communities that variability and uncertainty enter the assessment process at every stage (van Veen *et al.*, 2001). Therefore, while risk assessment is frequently portrayed in the science and regulatory literature as being founded in scientific principles it is in reality a combination of science and expert judgement, a situation that is recognised by many within the risk analysis community (Kraus *et al.*, 1992).

The growing awareness on the part of regulators and government of the underlying assumptions that are present in the assessment process and an acknowledgement of the limitations of current methods have led to a call from some in these communities for an assessment process that is based on more realistic exposure scenarios (IPCS, 2001; European Commission, 2004a).

1.22 Concern surrounding exposure to low-levels and chemical mixtures

A growing area of concern that has been highlighted by scientists and activists is the study and regulation of chemical mixtures. Although it is widely acknowledged that humans are continuously exposed to chemicals occurring in combination, at a variety of concentrations and through different routes of exposure (van Zorge, 1996), many scientists and regulators have largely believed that due to the typically low

concentrations of chemicals individually present their impact on human health would be negligible. However, these assumptions that suggest exposure to low-levels of chemicals and exposure to mixtures is unproblematic are being challenged within the scientific literature (Henschler *et al.*, 1996; De Rosa *et al.*, 1998), with research beginning to indicate that synergistic interactions i.e. interactions that have an effect greater than simple addition, may be more prevalent than first assumed (Rajapakse *et al.*, 2002; Christiansen *et al.*, 2009).

While there is increasing concern, especially among environmental health activists, that exposure to low-levels and mixtures of chemicals may lead to illness such as Multiple Chemical Sensitivity Syndrome (MCSS) and Chronic Fatigue Syndrome (Bell *et al.*, 1999), such diseases have been difficult to characterise and have been contested within the medical sphere, often being described as 'invisible' (Barrett, 1997; Dumit, 2006). Indeed, the ambiguity in their aetiology has led many physicians to believe them to be symptomatic of psychiatric illness or even a physical reaction to childhood sexual abuse (Schottenfeld, 1987). Additionally, it is noted by Ashford and Miller (1998) that chemical related illnesses appear to disproportionately affect women, leading some advocacy groups to suggest that the lack of will to adequately investigate these illnesses is symptomatic of a system influenced by patriarchy, where women's health problems are marginalised or ignored[2].

Campaign groups have taken the reluctance of regulators to address these concerns as a challenge and have directly questioned medical and

[2] See the Women's Environmental Network (www.wen.org.uk).

scientific opinion through the campaigning for and undertaking of new environmental health research. Such efforts have included Community-Based Participation Research (O' Fallon and Dearry, 2002), the instigation of quantitative health risk assessments at community level (Elliott *et al.*, 1999) and the inclusion of environmental groups in the setting of national environmental health research (O' Fallon *et al.*, 2003). However, many campaign groups alongside scientists such as van Zorge (1996) and Feron *et al.* (2002) argue that the only way forward in the debate over the effects of exposure to chemicals is an overhaul of traditional chemical risk assessment methods.

This thinking appears to have begun to filter through at a European level, as can be seen in the recent “European Environment and Health Strategy” (European Commission, 2004a), and increasingly to the UK risk assessment community, where there has been a visible increase in discussions surrounding the issue of chemical mixtures at a government advisory level. For example, in a recent report that specifically considered the risk assessment of pesticide mixtures, the Committee on Toxicity (COT), a government funded advisory group, that works independently of the Food Standards Agency, acknowledged the complexity involved in the study of mixtures stating that it is often difficult to determine the potential toxic effects that may occur as a result of exposure. However, the COT concludes that in its opinion there is not a singular suitable approach for the risk assessment of chemical mixtures; rather specific problems will require individual solutions.

1.23 Pesticide exposure

A group of chemicals that embodies all the challenges faced in risk assessment is pesticides. A pesticide may be considered as any substance or mixture of substances intended for preventing, destroying, or controlling any pest that could harm food, human health or the environment (FAO, 1986). Although pesticides are released into the environment with the specific aim of harming or killing their target organism, it has been recognised that in many cases the effects are not limited to the target species but can result in adverse health effects in humans (Weisenburger, 1993; Colborn, 2006).

In this sense, the case of pesticides and the risk associated with their use is somewhat paradoxical. Scientific progress and the rise in intensive and mono-agricultural have seen a growth in both the development and use of pesticides, so that their application has become normalised and routine within Western European agriculture. The widespread use of pesticides is seen to have benefited society through increasing production levels and providing a level of food security within Europe that was not present prior to World War II. However, despite their commercial application over the past sixty years there remain uncertainties and risk surrounding their use and their effects on human health and the environment. It was for this reason that I chose pesticides, and more specifically pesticide residues[3], as a means to understand how changes in the British scientific advisory

[3] In the regulatory context food does not include water, which is regulated on a separate basis. Residues are the traces of pesticides that are found within the food chain as a result of pesticidal substances remaining on or within crops following their harvest and storage.

system and challenges posed by emerging scientific uncertainties are managed in the risk assessment process.

Pesticides are a large chemical group with a diverse range of applications, as such their assessment and regulation falls across a variety of regulatory domains. The manner in which they are politically organised has therefore dictated which aspects of pesticide assessment and regulation are considered within this thesis. As this thesis is primarily concerned with the assessment and management of pesticides found on or within food I will only be discussing pesticides that are classed as chemical substances as found in Part A of Annex II of the Directive 91/414/EEC. I will therefore not be discussing active substances consisting of micro-organisms, which includes viruses, as found in Part B of Annex II of the Directive 91/414/EEC[4]. I will also only be discussing those pesticides that are assessed using dose response data to determine threshold effects and are therefore not deemed carcinogenic.

Within England and Wales the risk assessment of pesticides is conducted within the Pesticide Safety Directorate (PSD) through the Advisory Committee on Pesticides (ACP). However, due to the wide ranging application of pesticides, there are now several agencies within England and the UK that work within the area of pesticide regulation and risk communication, each of whom have a different remit and agenda. For example, the Pesticide Residues Committee (PRC) is responsible for national surveillance programmes and crop sampling procedures

[4] Please refer to the Directive 91/414/EEC for further details (Office for Official Publications of the European Communities, 1991).

(Pesticide Residues Committee, 2009), whereas, the Food Standards Agency (FSA) is responsible for providing public advice surrounding exposure to pesticides within food.

As with chemicals more generally, a key area of concern with regards to uncertainty in the assessment of pesticides is the possible human health effects that may result due to exposure to multiple pesticides. There are currently over 350 approved active pesticide substances for use on food animals and crops in the UK alone (Committee on Toxicity, 2002b). It is therefore possible that consumers can be exposed to multiple pesticide substances or residues in any one meal or even through the consumption of a single piece of produce; a recent survey conducted by the US Department of Agriculture found that 73% of conventionally grown fruit and vegetables[5] were found to have at least one pesticide residue present, with apples more likely to contain four or more residues than three or less (Baker *et al.*, 2002). Therefore, in any one meal an individual is likely to be exposed to a mixture of pesticide residues, as opposed to one single substance.

While the majority of exposures are expected by regulators to be at or below the legally acceptable reference dose, concerns have been expressed in the scientific literature that similarly to other chemicals pesticides when present in a mixture may act in an additive or synergistic manner (Lydy *et al.*, 2004; Moser *et al.*, 2005). While the possibility of synergism is a recognised toxicological concern when humans are

[5] Over 90 000 retailing units of twenty types of fruit and vegetables were analysed for pesticide residues over the course of a decade.

exposed to multiple chemicals, it is most commonly expected to occur where exposure levels are relatively high. However, the recent report on the risk assessment of mixtures of pesticides by the Committee on Toxicity for the Food Standards Agency suggests that existing research that has focussed on the interaction effects at high doses may be unsuitable for use in the risk assessment of exposure to the lower levels that the public are likely to be exposed to on a regular basis e.g. through the consumption of multiple pesticide residues:

> The type of combined action or interaction found at clearly toxic levels may not predict what will happen at non-toxic levels, including levels only slightly lower than the lowest observed adverse effect level (LOAELs). (Committee on Toxicity, 2002b, p.7)

However, despite a growing body of scientific and advisory literature suggesting that exposure to mixtures of low-levels may be problematic the consumption of multiple residues and the potential for interaction is not routinely addressed by the standard single substance assessment approach favoured by the UK's pesticide assessment committee, the Advisory Committee on Pesticides (ACP). This gap was recently highlighted in the report by the Working Group on the Risk Assessment of Mixtures of Pesticides (WiGRAMP) which acknowledged that "there is a concern that the regulatory system for pesticides found in foods does not routinely address the toxic effects of different substances in combination" (Committee on Toxicity, 2002b, p. 5).

Additionally, in those instances where policies for assessing risk from mixtures are in place it has been suggested by some scientists that there is likely to be a high degree of uncertainty (van Zorge, 1996; Wharfe et al., 2004). This may in part be due to the amount of time and research that has historically been spent investigating such risks; compared to the research investigating the adverse effects of single substances, exposure to chemical mixtures has received only marginal attention

In the UK, despite an historical reluctance to investigate the potential effects of exposure to mixtures of pesticides, there has been a move towards considering this type of exposure in regulatory circles, both at a national and European level. For example, in 2000 the FSA set up the Working Group on the Risk Assessment of Mixtures of Pesticides (WiGRAMP) which published a report of its assessment in 2002 (Committee on Toxicity, 2002b). Since publication this report has become a key document that is used by the FSA to issue consumer advice regarding exposure to mixtures through the consumption of pesticide residues in food. The central finding of the report was that the risk posed by exposure to mixtures is likely to be small. However, this finding has subsequently been criticised for failing to give due weight to the uncertainty involved in assessing these risks.

A key concern raised by many public interest groups (Friends of the Earth, 2004a; Pesticide Action Network, 2004) regarding pesticide residues is the exposure faced by children; they eat more food per body weight than adults, including a higher proportion of fruit and vegetables (Lawrie, 1998). As such, dietary intake represents a major source of

pesticides in this age group (National Research Council, 1993). However, the FSA (2004b) draws upon the WiGRAMP report to stress that children, pregnant and breastfeeding women are unlikely to be more affected by exposures to mixtures than others, a finding that has since been contested (Pesticide Action Network, 2004). In relation to disputes over the effects of exposure to mixtures of pesticides all groups involved purport to have a scientific basis for their claims. However, it is apparent that different judgements have been made not only regarding the efficacy and utility of current assessment techniques but also in how evidence has been understood and applied to formulate risk management decisions and advice. It is therefore important to understand the basis of such judgements.

Within this section I have highlighted that although there are formal risk assessment procedures in place to assess chemical and in particular pesticide risk, there remain concerns surrounding the effects of chronic exposure to low-levels and mixtures, areas that are not routinely addressed within the current pesticide risk assessment practices, which focus on the assessment of single chemicals. However, despite these concerns, the Food Standards Agency has advised that the risks posed by exposure are likely to be small, a conclusion that has been widely challenged. In the following section I provide an overview of the British scientific advisory system and how it has changed since the mid-1990s.

1.3 The UK scientific advisory system in flux

Since the mid-1990s it is possible to characterise the British advisory system as one that is in flux, a system that is still, ten years on, responding to the crisis in food safety management and the science-society relationship sparked by bovine spongiform encephalopathy (BSE).

On the 20th of March 1996 the British Government acknowledged that the ten new cases of variant Creutzfeldt-Jakob disease (vCJD) were likely to be attributable to the consumption of cattle infected by bovine spongiform encephalopathy (BSE) (Jasanoff, 1997a). Although there had been previous occurrences of CJD in Britain, the link between the new variant (vCJD) and the consumption of infected beef had been persistently down played by the UK Government. Since the late 1980s, the UK Government and its science advisors had repeatedly advised the public that beef was safe to eat, portraying the UK policy on BSE as being based on 'sound' science (Rothstein, 2003). However, subsequent STS analysis has revealed that the selection and interpretation of evidence used by the advisory experts was heavily shaped by the policy context in which it was created (Jasanoff, 1997a; Millstone, 2007), leading to the proposition that the failure of BSE policy was not accidental. Instead, it could be considered a result of longstanding inadequacies in the UK's approach to risk policy-making that resulted in both a crisis of legitimation and substance (van Zwanenberg and Millstone, 2005). For example, the Phillips Report that was charged with investigating the BSE crisis suggested that the failures in BSE policy were primarily a consequence of institutional failures of communication, whereby regulatory restrictions on

human and cattle consumption were introduced and enforced both too late and too ineffectively (Phillips, 2000). However, others, particularly those in the STS community, have argued that the science itself was and remains uncertain and incomplete, with the effect that policy which purported to be able to control risk was seen as unconvincing by the public (van Zwanenberg and Millstone, 2005).

On a wider scale, Rothstein (2003) has suggested that there were three identifiable institutional problems within the UK's food policy regime prior to the BSE crisis of 1996: first, the regime was undermined by the conflict of interest within the Ministry of Agriculture, Fisheries and Food's (MAFF), which was simultaneously responsible for both food safety and agricultural business; secondly, that MAFF had poor working relations with other branches of the UK Government, most notably the Department for Health, with the effect that they were not sufficiently joined up in their risk assessment practices and risk advice; thirdly, that there was insufficient transparency in decision-making processes, which when combined with regulatory failures encouraged public distrust in MAFF and UK food safety policy more widely.

In this sense, BSE starkly highlighted these shortcomings and acted as the catalyst for wider recognition of the need for change in the management of scientific uncertainty and risk in the UK. In 1997 in the wake of BSE, Robert May, the then Government's Chief Scientific Adviser, produced guidelines on the "Use of Scientific Advice in Policy Making" (Office of Science and Technology, 1997). Within these guidelines May stressed that there should be a move away from the confidential culture

within Whitehall and its agencies to a culture that promotes transparency within policy-making. This was stated as critical in situations where advice is uncertain or divided, so that the public are kept fully informed from the start of disagreements, and are better equipped to cope with shifts to the scientific consensus and changes to the surrounding policies (Science and Technology Select Committee, 2000). In the same year the James Report (James, 1997) was published, which was directly responsible for the establishment of the Food Standards Agency (FSA) and its three golden principles: independence; putting the consumer first; and being open and accessible to the wider public.

In 1999, following the election of Labour, the White Paper “Modernising Government” (The Cabinet Office, 1999) was published. The paper suggested that the policy process must be one of continuous learning and improvement, where policy-makers should be willing to “question inherited ways of doing things” and to make better use of evidence and research, focussing on policies that deliver long-term goals (ibid, Chap. 2). Such sentiments help illustrate the degree to which the controversy surrounding BSE became the impetus for change within the UK scientific advisory system. The most notable areas of change were in the call for greater transparency and the use of evidence-based policy, a term that suggests risk policy and advice is both objective and grounded in clear empirical research (The Cabinet Office, 2001; The Strategy Unit, 2002, pp.79-80). Additionally, reports such as “Risk and Uncertainty” (The Strategy Unit, 2002) indicate that there is a move within government to extend the boundaries of who can participate in policy debates through wider public or stakeholder engagement. Petts and Leach (2000)

document that in 1998 the UK Cabinet Office emphasised to central government and departments that consultation between stakeholder groups can lead to an increasingly realistic policy that is “better at reflecting peoples needs and wishes”. Similarly, the Royal Commission on Environmental Pollution (1998), in part drawing on STS literature surrounding the study of regulatory science and participation in environmental and risk decision-making, stressed in its document “Setting Environmental Standards” that government departments should adopt methods in environmental decision-making that account for values and lay knowledge, as well as technical or scientific expertise; a position that although increasingly democratic, creates new challenges and tensions surrounding the epistemic value of alternative forms of engagement and knowledge. The view expressed by the Royal Commission was formally articulated by The House of Lords Select Committee on Science and Technology who recommended in its 2000 “Science and Society Report” that:

> Direct dialogue with the public should move from being an optional add-on to science-based policy making … and should become a normal and integral part of the process (House of Lords Select Committee on Science and Technology, 2000).

Indeed, recent sociological and STS literature suggests that increasingly, science-based policy-making that does not involve participation by both experts and stakeholders, which may include the public, is being seen as not only ineffective but illegitimate (Buckeley and Mol, 2003; Irwin, 2006). However, relatively little work has been undertaken on how these

wider perceptions have actually affected the conduct of scientific risk assessment in specific areas of environmental regulation. Taken together with the challenges already described that have been posed from within the chemical risk assessment community itself, these changes form the backdrop to my investigation.

1.4 Research questions

The aim of this thesis is to critically evaluate how the twin challenges posed by changes in the organisation of the British scientific advisory system and by emerging scientific uncertainties in chemical risk assessment are managed in the case of risk assessment of pesticide residues in food, and to what effect. To undertake this, four research questions are considered:

1) How have the potential risks of pesticides been historically assessed and regulated in England and Wales since their first commercial use in the mid-twentieth century?
2) How are the potential risks of pesticide residues in food assessed in the current advisory system for regulation? Why has this system been challenged?
3) How do different advisory bodies use scientific studies of risk assessment to produce advice on the risks of pesticides and pesticide residues?
4) How are competing claims for scientific expertise and for lay involvement in risk assessment being handled in the case of pesticide residues?

1.5 Thesis layout

The thesis is divided into eight chapters. This first chapter provides an introduction to the thesis, setting out why pesticide residues have been chosen as a case study.

In Chapter Two I review existing work in the fields of environmental sociology and STS to explore the relationships between science, expertise and advisory decision-making and how the concept of regulatory science can be used to understand scientific decision-making. In the first part of the chapter I focus on UK food safety policy. In suggesting that policy problems are socially negotiated, I draw on existing literature to consider who it is that is allowed to participate in risk discussions, and the importance of expertise in obtaining authority in decision-making exercises. It is within this section that the role and expertise of NGOs is explored and it is highlighted that NGO staff are frequently scientifically trained, with the effect that their presence within advisory committees is somewhat ambiguous. In the third section, I critically examine the relationship between scientific facts and value judgements and explore how scientific uncertainty can be understood. Lastly, I discuss the subject of regulatory science and highlight the complex nature of science policy and the difficulties faced by advisors and policy-makers under conditions of scientific uncertainty.

In Chapter Three I provide a detailed overview of the methods used within this research - documentary analysis and interviews. Specifically, I discuss issues surrounding sampling and access, ethics and the difficulties in interviewing elites and obtaining grey literature. Lastly, I discuss how

the collected data have been analysed using a thematic approach that has drawn on the concept of framing and boundary work.

In Chapter Four, using documentary evidence, I explore the first research question: How have the potential risks of pesticides been historically assessed and regulated in England and Wales since their first commercial use in the mid-twentieth century? I aim to understand how historical decisions, such as the decision to classify pesticides as separate to other food and environmental contaminants and the decisions to maintain voluntary agreements until the mid 1980s, have shaped pesticide assessment and regulation as we understand it today. I suggest that despite significant technical and scientific advances, the fundamental questions that are being asked about the risks of exposure to pesticides through food have not significantly altered since the first review by Lord Zuckerman in 1953.

In Chapter Five I step behind the regulations to explore the toxicological science on which pesticide reference doses, and hence risk advice, is derived, and explore the challenges and uncertainty present in the risk assessment of pesticides as conceptualised by those working in this field. Using a combination of documentary evidence and interview data I answer the second research question: How are the potential risks of pesticide residues in food are assessed in the current advisory system for regulation and how has this system been challenged by those outside of the official process, such as NGOs?

In Chapter Six I move on to the stage following risk assessment to highlight how institutional practices can act not only as frames and boundary objects that help establish which areas of risk are seen as important, but can also determine which evidence is acceptable for use in providing advice. Using three case studies – advice surrounding exposure to pesticide mixtures, advice surrounding the peeling of fruit and vegetables, and advice surrounding crop spraying and bystander exposure – I examine the emerging tensions found between the official advisory system for pesticide regulation, as typified by the Advisory Committee on Pesticides, and other government bodies involved in assessing risk and providing advice, with specific reference to how these conflicts have been managed. In doing so I look to answer the third research question: How do advisory bodies use scientific studies of risk assessment to produce advice on the risks of pesticides and pesticide residues?

In Chapter Seven, I seek to answer the final research question: How are competing claims for scientific expertise and for lay involvement in risk assessment being handled in the case of pesticide residues? Having previously illustrated that the production of risk advice can lead to tensions not only between government bodies and NGOs but also between different bodies within government, I explore the factors that underlie these differences; perceptions of expertise, trust and epistemic authority. The chapter is divided into four sections: first, I consider what it means to be the 'right' kind of expert; secondly, I discuss barriers to groupthink; thirdly, I explore what happens when experts disagree;

fourthly, I consider the effects of widening participation in advisory committees to include lay members.

Finally, Chapter Eight draws the discussions from each preceding chapter together to consider how the evidence presented within the thesis answers the overall research question. Following this I consider the wider policy implications of this research and how it could be extended in the future.

Chapter 2: Regulatory Science and Expertise in Science-Based Policy-Making

2.1 Introduction

In the previous chapter, I highlighted that the scientific advisory system involved in pesticide risk assessment has come under pressure: first from other scientific, public and governmental concerns surrounding the need to consider realistic scenarios of low-level chemical exposure to multiple pesticide residues, and second, from the new demands for wider participation in the risk assessment process. These pressures have created a set of uncertainties, the management of which serves as the subject of this thesis.

In this chapter, I survey literature from Science and Technology Studies (STS) and allied fields that provide a way of conceptualising and further exploring the nature and management of uncertainty in areas where scientific knowledge plays a dominant role. The literature discussed is not definitive but has been selected for its relevance to the research questions posed in this thesis. The decision to ground my thesis in the field of STS was deliberate. Although the research questions specifically relate to pesticide residues as found in food, the underlying issues are essentially socio-scientific, concerning regulatory science, the treatment of scientific uncertainty and indeterminacy, and the interface between science and policy in risk assessment and risk management. All of these themes have been critically discussed in detail within the field of STS, although not always in relation to pesticides and very rarely in relation to

the risk assessment of chemical mixtures and more specifically mixtures of pesticides. In this sense I aim to use the literature (discussed in this chapter) as a working framework with which to understand and situate my own research. In doing so I should be able to highlight similarities and divergences between my empirical research and that which has gone before. Ultimately, in completing this thesis I will be able to extend the understanding found in the existing STS literature to the risk assessment of pesticide mixtures and hence add to the existing body of knowledge.

Although this thesis is primarily concerned with decision-making processes at the intermediate level of scientific risk assessment for regulation, rather than at the 'higher' level of decision-making at bureaucratic or political levels, it is important to understand why these formally separate functions may become blurred in practice and why science becomes politicised. For this reason, the chapter begins with a brief overview of the literature on areas of science-based policy-making (Jasanoff, 1986; van Zwanenberg, 1996; Jasanoff, 1997a; Sarewitz, 2004; van Zwanenberg and Millstone, 2005) where uncertainty and controversy around scientific evidence have been common features. Indeed, the debate around risks of pesticide residues in food mirrors these features with several actors questioning the scientific basis of policies that legitimise the use of pesticides, thereby drawing the ostensibly neutral risk assessment process into public scrutiny. The STS literature helps us understand such developments by highlighting the ways in which the scientific knowledge used to justify policy decisions is shaped by a number of tacit assumptions, practical constraints and value judgements.

The general overview of STS concepts in 2.2 is followed by a review of recent developments in British policy around environmental and health risk, and the role of scientific evidence. This helps to place the current controversy around risks of pesticide residues in the context of previous studies of controversies involving pesticide risk assessment and the wider critique that has been emerging over the traditionally closed and commercially focussed system of decision-making for food safety. The role of scientific risk assessment has come to be seen as part of this closed, industry-favoured system rather than as a corrective to it.

These criticisms have contributed to calls for wider engagement - section 2.3 reviews literature suggesting further complexities and ambiguities in how this engagement agenda is conceived. The nature of expertise itself has been opened up in recent work, so that the original notion of “lay expertise” seems to be insufficient in capturing the diversity of knowledge and skills that those labelled as ‘lay’ often appear to possess. The ambiguous role of NGOs at the interface between scientific experts and the ‘lay’ public is also outlined here. NGOs often rely on their use of science to gain authority in areas of scientific decision-making, however, in doing so the value judgements embedded in the science often remain concealed. This suggests that more attention must be paid to how scientific risk assessment is itself conducted.

The final section 2.4 reviews literature on the production of scientific knowledge in the context of regulation. The assessment of risk from exposure to pesticide residues can be described as an area of “regulatory science” (Weinberg, 1972; Ashford *et al.*, 1983; Jasanoff, 1990; Harris *et*

al., 2001); where “regulatory science” is used to describe the blurred area between science and policy, where questions may be asked of science but cannot be fully answered through its application. Key questions of interest that are covered within this section are therefore: 1) how boundaries are drawn between what is scientific and what is outside of science, and 2) how is uncertainty in risk assessment understood and represented.

2.2 Risk advice in the UK

In Chapter One, the area of pesticide risk assessment was shown to be contentious, an area where the scientific data are frequently challenged by those outside of the advisory process. Pesticide risk assessment is therefore an example of a science-based controversy, similar to others that have been extensively investigated within the field of STS – see for example, debates surrounding power plants (Nelkin, 1975), fluoridation (Martin and Richards, 1995), BSE (Jasanoff, 1997a), and climate change (Sarewitz, 2004).

At first glance, it is somewhat surprising that the area of pesticide risk assessment should be viewed as controversial as it is one where decisions are purportedly science-based, and hence could be considered as being grounded in objective evidence obtained through a neutral process. However, previous research in the area of science-based policy-making (Jasanoff, 1986; Wynne, 1992; Irwin *et al.*, 1997; Jasanoff, 1997a; Sarewitz, 2004; van Zwanenberg and Millstone, 2005) has questioned this image of value-neutral science, highlighting how social, political and pragmatic factors can influence the creation and assessment of scientific

knowledge for regulatory purposes. These influences mean that scientific data, such as those used in pesticide risk assessment, and science-based advice that is developed on the basis of these data can no longer be considered as simple representations of nature. Instead, they are seen as socially negotiated and containing a number of value judgements that may or may not be explicitly recognised and understood. Additionally, some authors such as Sarewitz (2004) and Jamieson (1992) suggest that controversy exists only when it is accompanied by a conflict in values and interests. This is key in the area of pesticide risk assessment where there are opposing views, regarding not only what level of pesticide exposure can be deemed acceptable, but whether the use of pesticides can ever by justifiable. In this sense, it is unsurprising that pesticide risk assessment is characterised by uncertainty and controversy.

A common method of managing the challenges posed by uncertainties in the evidence is to actually reinforce the role of scientific expertise and argue that only experts are capable of understanding and resolving them. However, this too provides challenges and can often lead to greater controversy as it is often unclear who it is that possesses the necessary expertise. Indeed, even looking within science for expertise presents challenges; science itself is not an homogenous entity but is divided into a multitude of disciplines each having its own ethos and value systems (Collingridge and Reeve, 1986). Each discipline is therefore only likely to best understand those parts and processes that fall into their remit. As such, experts are likely to understand the area differently and use different criteria to assess the validity of evidence.

These themes will be explored further in this chapter and throughout this thesis. In the following section, I will begin by considering developments in the British scientific advisory system which, at first sight, suggest that the notion of scientific advice as socially shaped is gaining wider credence and producing significant changes in how advice is organised and represented.

2.21 Scientific advisory practices

Recent developments in British science advice are partly grounded in a wider movement promoted by the Labour Government for rethinking the philosophy of making public policy. A major White Paper entitled “Modernising Government” (The Cabinet Office, 1999) defined policy-making as the process by which governments translate their political vision into programmes and actions to deliver 'outcomes' or desired changes in the real world. To achieve this goal the paper suggested that the policy-making process must be one of continuous learning and improvement, an open process where policy-makers should be willing to “question inherited ways of doing things” and to make better use of evidence and research, focussing on policies that deliver long-term goals (ibid, Chap. 2). Similarly, in a report on “Risk and Uncertainty” (The Strategy Unit, 2002), the then Prime Minister Tony Blair wrote that a priority for policy-makers must be to better manage risks and so minimise the likelihood of expensive crises such as that presented by bovine spongiform encephalopathy (BSE).

The BSE crisis is widely acknowledged in science policy literature as a catalyst for attempts to change entrenched procedures in the management of scientific uncertainty and food risk in the UK, and hence UK food safety policy. In 1997 in the wake of BSE, Robert May, the then Government's Chief Scientific Adviser, produced guidelines on the "Use of Scientific Advice in Policy Making". Within these guidelines May stressed that there should be a move away from the confidential culture within Whitehall and its agencies to a culture that promotes transparency within policy-making. This was stated as critical in situations where advice is uncertain or divided, so that the public are kept fully informed from the start of disagreements, and are better equipped to cope with shifts to the scientific consensus and changes to the surrounding policies (Science and Technology Select Committee, 2000). In the same year the James Report (James, 1997) was published, which was directly responsible for the establishment of the Food Standards Agency (FSA) and its three golden principles: independence; putting the consumer first; and being open and accessible to the wider public.

Following BSE, government risk advice has become associated with evidence-based decision-making (The Cabinet Office, 2001; The Strategy Unit, 2002, pp.79-80). However, there are key tensions in how the concept is understood. The use of phrases such as "evidence-based decision-making" suggests that previous policy decisions were made in the absence of evidence or an evidence-based framework. However, I will show in the following chapters that this is a misleading proposition for pesticides, where decisions have historically been grounded in scientific evidence-based risk assessment, albeit to varying degrees and under

different political frameworks. In the context of pesticide residues, evidence-based policy-making is therefore not a new concept; rather it appears to represent a commitment on behalf of the UK Government to ensure that the process of decision-making is transparent, accountable and engaging.

The appeal for openness marks a clear rhetorical shift away from the model of decision-making that dominated UK agrochemical policy and food safety policy more generally between the 1960s to mid-1990s, a model which Jasanoff (1997a, p.228) has previously described as operating within an environment that was “closed, cooperative, informal and consensual”. Here, policy decisions surrounding risks associated with agrochemicals have been shown to have been made on the advice of a small number of scientific experts, often affiliated to the industries being regulated (Gillespie *et al.*, 1979; Jasanoff, 1986; van Zwanenberg, 1996; Jasanoff, 1997a; Millstone and van Zwanenberg, 2002). This situation led many to suggest that the advisory system used to create policy did not always favour the consumer (Jasanoff, 1997a; Millstone *et al.*, 2000).

However, while this advisory environment has been criticised, it has also been praised. For example, prior to the public outrage over BSE, Jasanoff (1986) had argued that in comparison to the adversarial advisory system of the US, the closed British style system offered a number of advantages: namely that use of a closed system dominated by experts can reduce technical controversy and make government decision-making and risk management more efficient. However, she (ibid) also recognised the negative aspects of this approach – a lack of public engagement and

control over political and value choices and undue influence of industry – all of which were highlighted as problematic in the wake of BSE. In particular, it has been argued by several social and STS researchers (Millstone *et al.*, 2000; Millstone and van Zwanenberg, 2002; Rothstein, 2003) that this closed environment enabled policy-makers to both conceal uncertainty surrounding decisions from the public and place responsibility for decisions surrounding issues of food risk on the scientific advisors through presenting food safety decisions as being based on *"sound science"*; a phrase that is rarely defined (Michaels and Monforton, 2005).

The appeal to sound science can be seen as a method of limiting political disputes through presenting decisions as being based on facts that cannot rationally be opposed (Collingridge and Reeve, 1986; Nelkin, 1992). However, as more scientific evidence is generated, the number of political disputes can actually increase, as the science can be variously interpreted and used to support a variety of political arguments and risk management approaches, all of which can be presented as being based on "sound science" (Collingridge and Reeve, 1986; Sarewitz, 2004; Krimsky, 2005). The reliance on sound science within government, as a means of legitimising policy decisions, can also be used as a means for inaction; if there is seen to be an absence of sound science then there is justification not to regulate areas where evidence of environmental harm or risk to health remains uncertain. This type of use of science to avoid regulation has been widely criticised by those promoting approaches enshrined in the Precautionary Principle, which is described by the European Commission as a principle that:

> [The precautionary principle] may be invoked where urgent measures are needed in the face of a possible danger to human, animal or plant health, or to protect the environment where scientific data do not permit a complete evaluation of the risk. It may not be used as a pretext for protectionist measures. (Europa, 2005)

These tensions surrounding the proper interpretation of uncertainty in scientific evidence have been shown to be prevalent in the history of UK pesticide regulation, where advisory bodies such as the Advisory Committee on Pesticides (ACP) have been shown to be reluctant to act upon scientific evidence that does not explicitly show a causal link between exposure and effect (Gillespie *et al.*, 1979; Jasanoff, 1986; Irwin, 1995; van Zwanenberg, 1996); hence a lack of evidence can be presented as a lack of sound science.

Additionally, previous studies on the scientific advisory system surrounding the risk assessment of pesticides in the UK that have considered the role and remit of the ACP, such as that conducted by Gillespie *et al.* (1979), Irwin (1995) and van Zwanenberg (1996) have shown that there is a reluctance within these committees to consider evidence alternative to that provided by industry and regulatory sources, and that there is an over reliance on certain types of formal expertise, namely toxicological. Both these factors may compound the situation described above as they may further limit what scientific evidence is considered as acceptable or ‘sound’.

It is frequently argued within STS that the monopolisation of policy-making by those considered as expert may lead to a narrow definition of the problem, which in turn will affect any likely solution (Jasanoff, 2000; Millstone, 2007). Consequently, the exclusion of non-experts in decision-making exercises may result in the proposal of solutions that are unsatisfactory to those on the outside of the process. To address this problem, theories such as Beck's reflexive scientisation (Beck, 1992) advocate a de-monopolising and democratisation of science to allow wider participation in risk decisions. Through such involvement stakeholders such as campaign and public interest groups could become co-producers in the construction of knowledge (Hajer, 1995; Bäckstrand, 2004; Jasanoff, 2004).

If one accepts that to a greater or lesser extent policy problems may be socially constructed and that the nature of problems may differ depending on who is involved in their construction then it is critical to establish which actors have been involved in the policy process. In the following section I examine who has traditionally been allowed to participate in science-based policy-making and on what basis. I begin by considering why wider engagement might be desirable and then explore how experts and non-experts have traditionally been differentiated. Lastly, I consider NGOs and where they are positioned in terms of expertise.

2.3 A case for wider engagement?

The issue of wider, and in particular greater public and lay participation in science-based policy-making has been extensively considered and

discussed within the STS literature (as will be illustrated in this section), and it has been argued within STS (Cohen and Galusky, 2010) that the increased public visibility of this literature has been influential in encouraging a more discursive and critical appraisal of government and regulatory decision-making processes by both those within and outside of government. For example, the use of STS literature in documents such as the Royal Commission on Environmental Pollution's "Setting Environmental Standards" report (RCEP, 1998), which draws heavily on STS literature to highlight the underlying assumptions found in risk assessment and perceived benefits of adopting a more transparent and participatory assessment framework, suggests that the STS literature in this area is now being used by some advisory bodies and government departments to justify a call for the development of a more transparent and participatory culture in UK science-based policy-making.

The recognition that STS research can influence and ultimately alter the area it studies has led many STS researchers to struggle to "define the relationship of their research to the thing being researched" (Cohen and Galusky, 2010, p.2). Indeed, some, such as Mohr and Raman (2009), have argued that members of the STS community need to remain reflexive when making "critical sense of public engagement exercises" as they are increasingly playing a mediating role – see for example, the role of STS scholars at Lancaster University in the NanoDialogues project (Wilsdon et al., 2005). This new dynamic suggests that STS researchers are often in a privileged position where they can not only observe, theorise and comment on their field of research but also participate and instigate change, a position however, that requires reflexivity and

responsibility, and a greater awareness of the policy implications of their research.

In this section I consider the recent move by the UK Government towards wider engagement within scientific advisory committees and science policy more widely, to include not only different types of expertise but also 'lay' experts. I discuss that in the advisory areas surrounding pesticides the original notion of "lay expertise" seems to be insufficient for capturing the diversity of knowledge and skills that those labelled as 'lay' often possess. In the later part of the section, I explore the ambiguous role of NGOs who sit at the interface between scientific experts and the 'lay' public.

Reports such as "Risk and Uncertainty" (The Strategy Unit, 2002) indicate that there is a move among those in government to extend the boundaries of who can participate in policy debates through wider public or stakeholder engagement. Indeed, increasingly science-based policy-making that does not involve participation by both experts and stakeholders, which may include the public, is viewed by some as not only ineffective but illegitimate (Shrader-Frechette, 1991; Beck, 1992; Buckeley and Mol, 2003; Irwin, 2006).

Petts and Leach (2000) document that in 1998 the UK Cabinet Office emphasised that consultation between stakeholder groups can lead to an increasingly realistic policy that is "better at reflecting peoples needs and wishes". Similarly, the Royal Commission on Environmental Pollution (1998) stresses in its document "Setting Environmental Standards", that

government departments should adopt methods in environmental decision-making that account for values and lay knowledge, as well as technical or scientific expertise. This view was also expressed in 2000 by the House of Lords Select Committee on Science and Technology who recommended that:

> direct dialogue with the public should move from being an optional add-on to science-based policy making … and should become a normal and integral part of the process (House of Lords Select Committee on Science and Technology, 2000).

As I have noted, a key driver for the consideration of wider engagement was the BSE crisis of the mid-1990s and the realisation (that in part was influenced by the growing STS literature in this area) that decisions that are underpinned by scientific uncertainty carry wider social and ethical implications. Within the field of STS it is accepted that science alone is not the solution to complex risk problems. This situation has been widely discussed, being labelled by Funtowicz and Ravetz (1993) as "post-normal science"[6]. They argue that the inherent uncertainty in the knowledge used to produce decisions increases the difficulty of separating facts from value judgements. Post-normal science therefore occurs at the science policy boundary and can be applied to areas such as food safety, where policy decisions carry large public safety implications. Ravetz (2002) argues that the uncertainty in the risk assessment process and

[6] The term 'post-normal' is used to describe a situation where any decision made may carry consequences both known and unknown to the natural and social world.

the dependence on statistical analysis may not adequately represent the reality of the risks that we are exposed to. A solution to this, as advocated within the post-normal framework, is to extend the boundaries of who may participate in the decision-making process (Stern and Fineburg, 1996).

Collins and Evans (2002) argue that an overriding theme since the early 1970s in discussions around science-based decision-making has been the "Problem of Legitimacy". They are here referring to the need to look beyond the use of technically qualified in decision-making to increase political legitimacy. Benefits other than that of legitimisation have also been linked with widening the sphere of participation. For example, Sarkission *et al.* (1997) note that stakeholder participation can promote a better understanding of a project and its implications. This may help resolve or avoid potential problems through the consideration of previously unconsidered drawbacks and limit public disapproval so reducing the likelihood of costly delays. They go on to state that participation may increase cooperation between stakeholders resulting in a higher degree of trust between stakeholders and increased transparency of the decision-making process.

Despite the reported benefits of wider inclusion, as discussed above, many have been critical of this participatory turn. For example, some such as Collins (1988) and Poppy (2000) have set out a case for returning experts to their 'proper' role in technical decision-making, arguing that public participation can at times be misguided as the public may not have the necessary expertise with which to critically evaluate scientific

information. Poppy (2000) claims that "(while) complexity of assessing risk is well understood by specialists (it can be) somewhat misunderstood by non-specialists". By contrast, those such as Wynne (1996; 1998) and Irwin (2006) have argued that despite the rhetoric the role of alternative and lay expertise remains marginal in scientific discussions and decision-making.

More recently, in a discussion paper exploring the move towards wider participation in risk regulation and policy, Rothstein (2003, p.1) concludes that although widening participation may increase public confidence in a regulatory regime, "broadening participation per se does not necessarily produce more democratic or robust policy outcomes than closed processes". Irwin (2006) has also suggested that there is a lack of clarity surrounding widening participation, which has resulted in a discursive struggle emerging around what counts as "legitimate talk" and how talk should be constructed within public engagement. In particular, he highlights how the twin goals of consensus building and the call for the greater involvement of 'innocent' citizens, as opposed to activists, have created tensions and an often simplistic, homogenised view of the public.

Given that there remain significant challenges to extending participation it is important to consider what the desired goal is in any discussion forum and who may have a useful input in constructing policy choices.

2.31 Lay-experts and the 'public'

Typically, experts are those who hold some formal qualification that has required assessed training. Therefore, when experts are called as a witness or to provide evidence in decision-making there is an assumption that their advice represents only their professional knowledge. Conversely, lay knowledge may be simplistically defined as embodying a concern from the subjective standpoint of lay-people or non-experts (Williams and Popay, 2001). However, it may be better thought of as referring to knowledge that is shaped not by training or education but by the events and experiences of everyday life (Corburn, 2003). Traditionally, expert and lay knowledge may also be distinguished through methods of knowledge verification; while expert knowledge tends to be tested through methods such as peer review or a Popperian style of falsification, the nature of lay knowledge makes it difficult to formally validate.

While it might be tempting for policy-makers to homogenise the public into one undifferentiated mass this has been criticised as insufficient in describing the diverse nature and experience of the population as a whole (Petts and Leach, 2000). Sociologists, such as Wynne (1998), in his much cited study of Cumbrian hill sheep farmers and the assessment of radioactive fallout from Chernobyl, have shown that in many cases those considered as lay may have their own form of knowledge that could be equally as important as that of experts who possess more traditional technical training (Wynne, 1996). In such cases it may be more appropriate to abandon the term 'lay expertise' and consider them as experts in their own right; although they may have no formally

recognised qualifications, they are different to the population as a whole having specialised knowledge or being found in small specialist groups.

Collins and Evans (2002, p.254) have considered this conundrum in relation to their own experience as science studies scholars and suggested that expertise can be distinguished into three categories:

1) No Expertise: That is the degree of expertise with which the fieldworker sets out; it is insufficient to conduct a sociological analysis or do quasi-participatory fieldwork.
2) Interactional Expertise: This means enough expertise to interact interestingly with participants and carry out a sociological analysis.
3) Contributory Expertise: This means enough expertise to contribute to the science of the field being analysed

Such categorisation suggests that there are no clear boundaries that determine who can be considered expert. However, Collins and Evans (ibid) argue that we should not become 'paralysed' by this but should use these categorisations as a tool to help consider the inter-relationships between actors. Importantly, it should be noted that although this description provides a useful working framework in exploring the notion of expertise, Collins and Evans appear to overlook one distinct type of expertise that is often present in policy making – *procedural* expertise. This type of expert does not necessarily require *interactional* or *contributory* expertise as their role is to challenge existing working

practices, as opposed to contributing to technical discussions. Within this thesis I will consider how these categorisations may reflect those working within the sphere of pesticide assessment and management.

While highly contested, there is therefore in practice a distinction made between those considered expert, lay-expert and non-expert. However, the campaigning NGOs[7] are one group who are often involved in the policy process that arguably do not sit comfortably in any of these categories. With the notable exception of Yearley's research (1992 -a; 1992 -b; 1996) there has been little work that considers NGOs as scientific actors or examined their role in governance. However, this is beginning to change with researchers such as Eden, and Lane and Morrison investigating the expertise of NGOs and their role in policy (Eden *et al.*, 2006; Lane and Morrison, 2006). It has been argued that in the current political culture, faith in hierarchical policies has decreased, leading towards an increase in governance that can be characterised by networks of decision-making relationships that link government and civil society (Marsh and Rhodes, 1992; Buckeley and Mol, 2003; Eden and Parr, 2006). The theory of ecological modernisation suggests that as governance becomes horizontal, policy is likely to be increasingly mediated through non-state actors, so that the importance of NGOs in shaping policy decisions increases (Hajer, 1995; Buckeley and Mol, 2003). Lane and Morrison (2006) suggest that the result of this shift is that

[7] The definition of an NGO has been taken from Lane and Morrison (2006) who define NGOs as non-state or non-profit organisations that have been traditionally composed of volunteers and concerned with distinct policy objectives. See: (Lane and Morrison, 2006)

NGOs can now be viewed as playing one of three roles: *service providers* to citizens through supplementing the government; *partners* to the government in the provision of public goods; and *challengers* to the government in demanding accountability and changes to public policy. Yet while NGOs can be identified as organisationally different from 'unorganised' or 'innocent' citizens (Breckenridge, 1999; Irwin, 2006), it can be argued that they are often included in policy-making exercises not because they possess expertise, but because they represent a particular value system that is shared by their members, in some cases both reasons may be used to justify their inclusion. In this sense, their role is often somewhat ambiguous as they may be viewed as either an expert or public representative or a hybrid of the two.

Indeed, affiliation by researchers to such a group can often have negative connotations and has traditionally been used as a tool to undermine a researcher's credibility, through labelling work conducted for or in conjunction with an NGO as 'unscientific' (Eden, 2005). An example of this is seen in the response provided by Milne (1993), an industrial chemist, to Wynne and Mayer's (1993) article on how science fails the environment. In reference to Mayer, then an employee of Greenpeace, Milne (ibid, p.27) writes that "the Greenpeace approach is not anti-science…but neither is it science. So what is it? It is moral philosophy at least, and religion probably. All that scientists can say to Greenpeace is: sorry, your application for membership of the scientific community has been carefully considered – and rejected". Here, Milne is clearly signalling a boundary being drawn between real science undertaken by experts and

science undertaken by Greenpeace, an NGO, that is at best value laden and at worst not science at all.

However, studies into the scientific legitimacy of NGOs (Yearley, 1992 -a; Eden, 2005; Eden *et al.*, 2006) have shown that far from being just consumers of science many NGOs produce, consume and publish scientific research, with many of their staff having formal scientific training (Eyerman and Jamison, 1989; Yearley, 1992 -b). Therefore, they can no longer be derogatively described as 'pseudo-scientists', as was the case when Mellanby (1974) warned of the harm that may be done to the credibility of 'real' scientists by the actions of others, who adopt the use of scientific jargon to promote their own objectives, while having no formal science training. Although many NGO scientists might not describe themselves as an 'expert' in the traditional sense, they may recognise themselves as 'intelligencers'[8], producers of intelligence, rather than science for the people. If NGOs are indeed active in the production and dissemination of scientific information then their position as non-experts or even lay-experts is open for questioning.

An earlier article by Yearley (1991) highlighted that environmental researchers working for NGOs will often argue that evidence used in debates is based on "objective reasoning" and that "scientific expertise remains the principal form of legitimation in the leading environmental organisations". The use and production of scientific evidence and in-house expertise by NGOs to challenge current practices or make policy

[8] Taken from Eyerman and Jamison (1989, p.114), meaning a hybrid between a professional scientist and a movement activist.

recommendations can therefore be seen as a form of reflexive scientisation allowing NGOs to become alongside other stakeholders, co-producers of science and scientific knowledge. However, such observations also suggest that some NGOs are becoming dependent on science and scientific practice as a means of legitimisation. Such a proposition leads one to propose that far from being anti-science, as suggested by Milne's comments, NGOs are in danger of reifying science so that the social negotiations involved in arriving at scientific 'facts' are lost in their discussions.

Eden *et al.* (2006) argue that environmental NGOs reflect a mode 2[9] style knowledge production, as described by Gibbons *et al.* (1994), as they desire knowledge to be socially accountable and practically useful in environmental governance. In response to this the authors (ibid) suggest that NGOs do not focus on the complexities and inner workings of science but its interpretations and consequences, with NGOs seeing their role in the production of knowledge as producers of policy relevant research. However, knowledge obtained through a mode 2 style production can have drawbacks with producers facing difficulties in validating their research, as legitimacy techniques used under mode 1 such as peer review are often not available.

[9]Gibbons *et al.* argue that there have been fundamental changes in the way that scientific, social and cultural knowledge is produced, which can be characterised by an increase in features such as reflexivity, trans-disciplinarity, and heterogeneity. Thus, mode 2 knowledge production is undertaken in the context of application and places science policy and scientific knowledge in its broader societal context. However, it should be noted that the universality of this concept has been questioned.

Yearley's (1996) study of conservation NGOs also suggests that NGOs operate using an "epistemological flexibility" that allows them to be pragmatic in whether they choose to accept or deny the validity and authority of science. The tactic of using science as a discursive medium allows NGO actors to obtain authority in a debate where they might otherwise be viewed as non-experts and so be prevented from participating in any discussions.

The appearance of expertise is important in obtaining and maintaining authority in any debate as it allows access to any formal negotiations, such as those involved in creating policy recommendations. Worcester's (2001) research[10] appears to confirm Jasanoff's (2003) suggestion that the credibility of expertise is built upon civic epistemology[11] in highlighting that the public place more trust in scientists working for NGOs than they do in those working for government or industry. This suggests that the public do not base their opinion simply on the scientific evidence presented to them but are influenced by the context in which such knowledge is produced and communicated. If NGOs can be considered not just as public representatives but as possessing their own expertise, we need to ask ourselves what role do they or should they play in the policy process? When they are included is it because of their scientific and expert knowledge, or is it because of the social values that

[10] This research by MORI collated general public survey data collected both within and outside the UK and was used in the Jenkin Report. See (House of Lords Select Committee on Science and Technology, 2000)

[11] Civic epistemology is defined here as the criteria by which members of society evaluate the validity of public knowledge.

they represent and bring to the discussion? If NGOs are there because of the values that they represent, is this made explicit and how does this affect their ability to influence or steer policy discussions?

In this section I have highlighted that although there has been a move among policy-makers (in part as a result of STS discussions) to consider widening the sphere of participation, wider participation remains ill defined as it is unclear who should be included and what their role should be. Through claiming expertise, it appears that actors are able to obtain power and authority in a debate that is largely denied to those considered as possessing no or only lay expertise. In discussing NGOs I suggest that science and scientific expertise is a powerful tool by which actors can obtain or borrow authority and so present themselves as competent actors who should be included in any policy discussions. However, an over reliance on science and scientific practice by NGOs may result in a situation where the social element of scientific research and the construction of scientific facts becomes lost and where any value judgements embedded within such 'facts' become overlooked.

2.4 Scientific uncertainty: conceptualisation and management

In the previous sections I have discussed changes in UK food safety policy, suggesting that policy problems are in part socially negotiated. In the following, I critically examine the relationship between scientific facts and value judgements and investigate the role of scientific uncertainty, risk and error in advisory decision-making. In doing so, I seek to illustrate

that scientific uncertainty is often not due to an inadequate amount of research but a result of the initial problem framing; inappropriate or un-reflexive questions being asked or inappropriate methodology being adopted to answer these questions. In the latter part of this section, the discussion moves on to consider the area of regulatory science and how the principles employed in this area may help overcome the effects of scientific uncertainty.

2.41 The blurring of boundaries

It is widely acknowledged within STS that knowledge produced by science can never be independent from society and the political and regulatory context in which it is obtained. As such, it has been argued that there is a need for a continuous renegotiation in politics of the boundaries between science and policy (Jasanoff, 1987; Dickson, 1988; Jasanoff, 1996). One difference between science and politics, as discussed by Sarewitz (2004), is that whilst political debates allow participants to draw on a range of arguments including scientific fact, personal values and experience, those involved in scientific debates are required to suppress the open discussion of value preferences to avoid science and politics becoming synonymous with each other. However, while there is often an attempt to keep these boundaries separate, research such as Jasanoff's (1990), on the adversarial relationship between scientists and regulators in the U.S., indicates that the blurring of boundaries can sometimes result in increasingly productive policy-making.

It can be argued that the separation of science from non-science is not a set of essential methodologies or code of practice but an array of circumstances and strategic behaviour known as “boundary work”, where success is measured by the prevention of science being controlled by outside powers (Gieryn, 1995). In other words, the challenge for science is to move closer to politics whilst retaining its autonomy. Mukerji (1989) illustrates this symbiotic relationship of science and politics through highlighting how just as a scientist’s authority is legitimated through the use of science in policy-making so too are government officials able to legitimise their decision-making through presenting them as being based on expertise and scientific facts. Indeed, Gieryn (1995, p.436) aptly surmises, “only good fences keep politics and science good neighbours”.

Boundary work is therefore utilised by competing groups, such as scientists or NGOs, to challenge scientific credibility and so discredit unwelcome policy initiatives. However, in doing so they must, to retain the legitimacy of their own claims, preserve the cultural authority of science. Gieryn (1995) shows that this is achieved through the creation of two abstract spaces; one for scientific practice and findings that are labelled as ‘bad’ and a second space for real or ‘good’ science. Through the construction of artificial boundaries that separate ‘good’ and ‘bad’ practice, the authority of science and the expert status of scientists is retained allowing the ‘good’ science to be used in policy-making and advisory decision-making. Boundary work can therefore be seen as providing a methodological approach that enables us to explore how different evidence is perceived and used and how different forms of

expertise are understood; this approach is discussed further in Chapter Three.

2.42 Classifying uncertainty

As I suggested in Chapter One, in the discussion surrounding risks from pesticides, advisory and risk decisions are frequently taken when scientific evidence is uncertain or contested. In the following I consider the different ways in which uncertainty is understood and represented, showing that even within the field of STS there are disagreements over how best to conceptualise and manage uncertainty.

I shall first consider Renn's definition of uncertainty. In discussing hormesis and risk communication, Renn (2003 p.18) suggests that there are "three phenomenological components of any risk debate": complexity, uncertainty and ambiguity – see Table One.

Although Renn acknowledges a role for stakeholders in the resolution of uncertainty, his characterisation of uncertainty suggests that it can only be reduced through increased use of expertise and the production of more, higher quality, scientific data, i.e., it suggests that uncertainty can be reduced through more research. When considering the challenges that face pesticide risk assessors – inability to prove causation for real life exposures – Renn's model suggests that it is not uncertainty that is the underlying problem in this area, but 'complexity'. Similar to that of uncertainty, Renn's proposed solution is to apply increasingly sophisticated scientific methods and greater use of expert skills. Similar

solutions were frequently proposed by many of the expert advisors that were interviewed during this research, as will be discussed in greater detail in the following chapters.

Renn's conceptualisation has been criticised by some such as De Marchi (2003 p.26), who suggests that the presence of 'complexity' implies both a move towards post-normal science and "the coexistence of plurality of legitimate perspectives" in any risk debate. While Renn views such plurality as resulting in ambiguity, De Marchi (2003) goes further, highlighting the importance of how problems are framed in any discussion of risk. She stresses that different framings, all of which may be legitimate, require the risk assessor to be aware not only of uncertainty but also of ignorance. De Marchi (ibid) therefore argues that the way that risk problems are initially framed can affect the whole process of assessment, from experimental design through to the rejection or acceptation of a hypothesis. In this sense, she states (p. 26) that "scientific risk assessment neither examines nor explains reality in its whole, but approaches it by (scientific) methods of approximation and selection".

Table 1: Renn's phenomenological components (Renn, 2003)

Component:	Description:	Renn's proposed Solution:
COMPLEXITY	Difficulty in identifying and quantifying causal links between different chemicals and specific effects. Occurs where direct observation of cause and effect is unlikely. This may be due to chemical interactions in the environment, delayed reaction, differences in individual responses etc.	EPISTEMOLOGICAL DISCOURSE Increased use of sophisticated scientific investigation. Need for the use of mathematical tools such as extrapolation and fuzzy set theory. Requires deliberation among experts with technical skills.
UNCERTAINTY	Probabilities are not accurately able to predict uncertain events, with predictions characterised by the inclusion of other unknowns i.e. missing data. Uncertainty acts to reduce confidence in the cause and effects chain. It therefore increases when complexity increases. Is linked to indeterminacy.	REFLECTIVE DISCOURSE Requires involvement of experts and the production of new and better scientific knowledge. Also requires the inclusion of stakeholders and the public to gain a wider view on acceptable levels of protection. There can be no scientific answer to what is considered acceptable as it involves societal values.
AMBIGUITY	Where different interpretations arise from the study/observation of identical data. Often does not refer to differences in scientific practice, rather what the data means in relation to human health and the environment.	PARTICIPATORY DISCOURSE Focus is on resolving value differences

The need to differentiate forms of uncertainty has been succinctly discussed by Wynne (1992 p.114), who proposes four types – see Table Two.

Table 2: Four types of uncertainty as defined by Wynne (1992 p.114)

Types of Uncertainty:	Description:
RISK	Where the odds are known
UNCERTAINTY	Don't know the odds; may know the main parameters. May reduce uncertainty but increase ignorance.
IGNORANCE	Don't know what we don't know. Ignorance increases with increased commitments based on given knowledge.
INDETERMINACY	Causal chains or networks open

Whilst Renn's (2003) definition of 'complexity' appears to be similar to Wynne's 'risk', Renn appears to conflate the other three types into one. However, Wynne (1992) is very clear that indeterminacy should not simply be viewed as large scale uncertainty, but as part of the foundations of all scientific knowledge, as such it can be present when the level of traditional 'uncertainty' is thought to be small. In making such a claim Wynne (ibid p.116) explicitly criticises Ravetz and Funtowicz's concept of post-normal science, which suggests uncertainty exists on a scale of small (risk) to large (ignorance). Instead, Wynne (ibid) views all four types of uncertainty as overlapping and perpetual, with each emerging in importance depending on the context of the decision-making. Indeterminacy is therefore seen by Wynne as pervasive and ever present

in scientific knowledge, however well it is concealed. In the context of pesticide risk assessment, Wynne's (1992, p. 116) concept of indeterminacy suggests that it "pervades even apparently purely technical questions", as such it is not enough to simply conduct a greater amount of scientific study in a bid to reduce uncertainty, as this fails to address the underlying problems.

In discussions surrounding risk and uncertainty it is important to consider the different types of errors that can be made and their implications. It is recognised that both Type 1 and 2 errors can occur during chemical risk assessment (Cranor, 1993; De Marchi, 2003), with Type 1 errors indicating a false positive where an effect is wrongly exhibited, and Type 2 errors indicating a false negative where an effect which should exhibit does not. Both types have repercussions in terms of how risks are assessed and advice produced. In addition to these two types of error a third type is now regarded as being present: Type 3[12], which relates to the framing of risk problems, the presence of 'ignorance', and the inability of risk assessors to account for unknown variables and processes in their decision-making.

Errors are important considerations in regulatory science as the occurrence of Type 1 errors may to lead to over-regulation, which is likely

[12] This concept has its origins in Kimball's (1957, p. 134) statistical concept that describes Type 3 errors as "the error committed by giving the right answer to the wrong problem" – see: Kimball, A.W. (1957) Errors of the Third Kind in Statistical Consulting. *Journal of the American Statistical Association,* **52** (278): 133-142.

to be expensive and over precautionary, while an excess of Type 2 errors is likely to lead to under-regulation, increasing the possibility of risk through exposure. Within the field of risk assessment there is an emphasis on avoiding Type 1 errors (false-positives), and it has been suggested that this is linked to a cultural philosophy regarding scientific progress and a demand for certainty:

> When the chances of false positives are kept low, a positive result can be added to scientific knowledge with considerable knowledge that it is not a random chance. Were one to tolerate higher risks of false positives, take greater chances of new information being false by chance alone, the edifice would be much less secure. (Cranor, 1993, p.33)

Hoffmann-Reim and Wynne (2002) discuss Type 3 errors in their article "In risk assessment, one has to admit ignorance". Here, using the case of the pesticide DDT they detail how the effects of DDT on avian reproduction were not detected, as this variable was never considered to be relevant in the original risk assessment. They suggest that the problem of tackling the unknown in chemical risk assessment is more pertinent and important in terms of maintaining credibility than the act of decreasing and quantifying known uncertainties. A situation which they state has been the traditional policy response, as it creates an illusion that risks are containable. Indeed, they make the following bold statement:

> Risk assessment and policy need to emphasize uncovering the limits to knowledge rather than proving existing knowledge to be correct. (Hoffmann-Reim and Wynne, 2002, p.416)

To achieve this they suggest widening participation and opening up the risk assessment process to increase its transparency and trust in the process.

As the above indicates policy decision-making can be difficult in domains characterised by uncertainty and indeterminacy (Jasanoff, 1990; Wynne, 1992), with some, like Rothstein *et al.* (1999), commenting that the scientific demands made by national policy-makers for definitive answers can itself increase scientific disagreement. Indeed, studies have shown that scientific uncertainty is commonly cited as a reason for inaction in policy-making (Oreskes, 2004; Michaels and Monforton, 2005) and can challenge both science and the authority of scientists (Shackley and Wynne, 1996); scientists can struggle to retain a technical rationality if they are simultaneously obliged to acknowledge the existence of uncertainty while minimising the assumption that this uncertainty poses a challenge to the legitimacy of policy-making. One device used by scientists to cope with this dual positioning is to perpetuate the belief that solutions are possible if only more scientific research is undertaken (Shackley and Wynne, 1996; Poppy, 2000; Oreskes, 2004), a solution that has already been highlighted as problematic (Wynne, 1992).

This belief that more research would solve scientific uncertainty can be seen as reaffirming and strengthening the authority of science by

deflecting attention away from a critique of scientific practice; here, the origin of uncertainty is not the scientist's methods but the complex natural systems that are under investigation. Therefore, it is not science or the social and political environment in which science is undertaken that is responsible for uncertainty but nature itself. This argument allows scientists to retain their position as experts as, they might argue, it is only through undertaking more rigorous science that that we can rid ourselves of such doubt. Such reaffirmation can also act to reinforce the importance of a particular policy order as in legitimising the act of scientific practice we also legitimise the policy that is built on scientific foundations.

Levidow (2003), has argued that in recent years scientific uncertainty has been more readily acknowledged, with its cause generally attributable to a lack of adequate scientific information. However, he rejects this hypothesis, arguing, like Wynne and Mayer (1993), that risk assessment is itself characterised by uncertainty. Similar to De Marchi (2003), Levidow (2003, p. 116) therefore proposes that uncertainty does not arise just from inadequate knowledge but is also a reflection of the underlying questions asked by the scientists and their selection of relevant facts, which he describes as 'value laden' choices. This view is shared by others researching food safety policy and pesticide risk assessment (van Zwanenberg and Millstone, 2000; Jensen and Sandøe, 2002; Ravetz, 2002).

Similarly, Jamieson (1995) has suggested that uncertainty can be viewed as politically and culturally contextual and can be the result of a

controversy rather than the cause of it. It has also been argued that scientists are more likely to express uncertainty if the science in question is not tied to policy uses (Shackley and Wynne, 1996; Sarewitz, 2004). On this basis Sarewitz (2004, pp.385) concludes that scientific uncertainty can be best understood "not as a lack of scientific evidence but as the lack of coherence among competing scientific understanding, which is amplified by the political, cultural and institutional contexts in which science is undertaken".

2.43 Regulatory science

In the previous sections I have discussed how science is used in the advisory process and policy-making. In doing so I have illustrated that there are often cases where the science required is either unavailable or uncertain. For many science-based decisions, such as those pertaining to risk management strategies and policies, science and evidence are often created specifically to answer particular questions. This type of regulatory science is discussed below.

Risk problems may be considered as 'trans-scientific', a phrase developed by Weinberg (1972) to highlight the existence of a blurred area between science and policy, where questions may be asked of science, yet cannot be fully answered through its application. Ashford (1983), has since provided a more detailed definition, as shown by Jasanoff (1987):

> Science policy denotes issues that are grounded in scientific analysis but for which technical data are insufficient to support

> an unequivocal scientific conclusion. The ultimate resolution of these issues depends on determination of social policy. (Ashford et al., 1983)

Questions may be unanswerable due to reasons such as a lack of scientific understanding or the inability to provide answers without disproportionate time and expense being spent on the solution. Weinberg's concept of trans-science appears to fit the process of chemical risk assessment well, as there is currently limited understanding of human exposure to low-levels and mixtures of chemicals, yet policy decisions must be made to prevent or minimise risks to human health.

Weinberg proposes that the answer to such problems is the creation of a distinct branch of science, that has been variously labelled as 'trans-science' (Weinberg, 1972), "regulatory science" (Jasanoff, 1990) or "mandated science" (Salter, 1988), where the demands for proof are lower than that of ordinary science. It is argued that this relaxation in the demand for and quality of evidence can potentially enable policy-makers to reach a decision without being burdened by the requirement of unattainable scientific proof. Irwin *et al.* (1997, p.19) have expanded this idea, stating that "regulatory science is concerned with how science can make predictions on the basis of uncertainties".

Although it is argued that the use of such a strategy can prevent indecision and inaction, its use raises difficult questions over the nature of science-based decision-making. For example, if the standards for assessing regulatory science are lower than that of ordinary science, how

can one be certain that the evidence used to reach a decision is reliable or wholly relevant? The use of this criterion also suggests that there is greater opportunity in the policy-making process for decisions to be based upon or influenced by the value judgements of those involved in assessing evidence. This raises similar questions about transparency and accountability as discussed earlier in the chapter.

Jasanoff's (1990) research on US science advisors involved in regulatory decision-making[13] suggests that regulatory science is rarely innovative or subject to standard checking procedures such as journal publication or peer review as found in a mode 1 style knowledge production. The absence of such correctional methods that are ingrained into the culture of pure or academic science may therefore result in the production of science that is either methodologically flawed or politically motivated to endorse a particular regime or course of action. This would appear to suggest that science specifically produced for regulatory purposes would not hold up to independent scrutiny by peers within that field. Conversely, while the use of regulatory science allows decisions to be made even

[13] Jasanoff's earlier work on chemical control in Europe and the US, suggests that traditionally the British style of regulatory science has been similar to academic science allowing decision-making to proceed even under conditions of uncertainty. This can be contrasted with the adversarial style system of the US, where it is easier to delay taking action. However, due to science based controversies such as BSE, and the rise in problematic science-based questions stemming from policy issues such as the environmental release of GMOs, these distinctions are beginning to be challenged with the UK and European systems becoming more openly adversarial like their US counterparts. See: (Brickman *et al.*, 1985).

under conditions of uncertainty it is possible that this very uncertainty will be used as a tool to delay action on the grounds that more evidence is needed.

Jasanoff (1990) goes further; in acknowledging the conceptual difficulty of drawing boundaries between branches of science she defines "regulatory science" as practical with its purpose being to produce techniques, processes and artefacts that further the task of policy-making. In doing so she highlights (ibid, p.77) three types of activity that are indicative of regulatory science; *knowledge production* to fill gaps that may be necessary for regulatory purposes, *knowledge synthesis* whereby existing primary scientific research is evaluated and assessed, and *prediction* which requires the decision-maker to determine the significance of any risk created by the regulation. Rothstein *et al.* (1999, p.243) use this definition to state that regulatory science can be viewed as "a problematic meeting ground between the institutional practices and professional expectations of science and of policy making". This point is similar to Shackley and Wynne's (1995), who suggest that it is more practical to consider what regulatory science represents rather than trying to define it by its purpose. Therefore, regulatory science is not just a hybrid between science and policy but is part of a larger process of "mutual construction" that varies across policy settings and decision-making processes (Rothstein *et al.*, 1999).

While the content of regulatory science differs from that of ordinary science, it is the context in which research and decisions are made that is most important. Regulatory science is dominated by the heavy

involvement of industry and government, and unlike academic research is often carried out in short time periods to meet a particular purpose as is highlighted by Jasanoff above. It is also often conducted at the boundary of existing knowledge and as a result can be more difficult than ordinary science to validate.

Rothstein *et al.* (1999) in their study on regulatory science, Europeanization and the control of agrochemicals agree that characterisations of regulatory science based on content or social function are too generalized. Through investigating regulatory science in action, they show that the domain encompasses a variety of activities wider in scope than science alone. In the example of the development and innovation of agrochemicals, they state regulatory science can involve a range of scientific, technical, legal and administrative activities that are increasingly international[14]. However, it remains tied together by relations of trust, expert knowledge and mutual understanding between those actors involved. Similarly, Irwin *et al.* (1997 p. 24) too, in discussing the regulatory science used in agrochemical risk assessment, state that chemical testing "interlinks social, bureaucratic and scientific demands", with the result that social assumptions "pervade the development of a technical regulatory regime". Here they are referring to the fact that both the means of production and presentation of scientific evidence for regulation is implicitly and explicitly shaped by social factors, such as institutional affiliation. Wynne (1992), goes further in stating that the use

[14] Rothstein *et al.'s* study is specifically concerned with regulatory science in the context of the Europeanization of the agrochemical industry.

of risk assessments for what he describes as “badly structured extensive problems, such as toxic waste or pesticides” have largely become artificial, with assessments and the resulting knowledge being constrained by pragmatic considerations, such as what is actually observable or measurable. In this sense, risk assessments are viewed as producing knowledge where variation and uncertainty have been artificially reduced. Wynne (ibid) therefore makes the suggestion that this can lead to a familiarisation of protocol among risk assessment practitioners that renders the true scale of uncertainty invisible and therefore removed from risk decisions.

Regulatory science can therefore be seen as having its own institutional practices that create new networks of knowledge users and producers. However, while there may be a variety of actors involved within the process, not all are equal participants. Irwin *et al.’s* (1997) study illustrates that actors such as NGOs are often pushed out of UK discussions due to a perceived lack of specialised expertise, an idea which as discussed earlier has been challenged (Yearley, 1992 -b, 1992 -a; Eden *et al.*, 2006). Conversely, industry groups who have a longstanding relationship with regulatory bodies and hence are heavily involved in regulatory discussions can be seen to subtly influence the decision process (Rothstein *et al.*, 1999).

These ideas of regulatory science will be used in this thesis to explore and understand the creation and application of science used in pesticide risk assessment.

2.5 Summary

In this chapter I have shown that regulatory science can be complex, involving a variety of actors who often have to exhibit specific expertise and prove their credibility before they are allowed to participate in science-based decision-making. To undertake science-based decision-making, STS literature suggests that science and scientific research has to be critically examined to understand how it has been produced and what the implications for policy are if it is used. Such a stringent examination of knowledge production may result in science being shown as weak and uncertain. Previous research suggests that this uncertainty is frequently used by competing actors, such as scientists, policy-makers, campaign groups and the public, to gain authority in a debate and to challenge other actors' right to participate (Jasanoff, 1987). However, studying these relationships and procedures can, as Jasanoff (1986) and Irwin *et al.* (1997) suggest, provide an insight into the changing nature of scientific practice and help us understand how scientific uncertainty is managed in the advisory and policy-making process.

This review indicated that there is a move among UK policy-makers to change the advisory and policy process so that there is not only wider engagement, but also more transparent decision-making that utilises a wider range of evidence. However, it has been observed that in order to have authority and be a credible actor in any science policy debate, a degree of expertise is often a prerequisite for involvement. Science expertise however, is frequently challenged, often using boundary work strategies to de-legitimise other experts' claims.

In this chapter I use the literature to suggest that science and values are inherently linked, with values and judgements shaping all aspects of science; from the initial framing of a problem through to choice of methodology to finally finding and agreeing upon a solution. The presence of scientific uncertainty has been shown to be a cause of inaction and a tool that can be manipulated within the advisory process. I have argued that uncertainty itself is complex, and needs to be understood in its social context. I further argued that the use of the principles found within the domain of regulatory science can be used to mediate scientific uncertainty and so prevent inaction, but illustrated that these principles themselves raise questions that range from issues of validation to the involvement of value judgements in public policy.

The themes discussed within this chapter will be applied to the area of UK pesticide residue regulation through the empirical study detailed in the following chapters.

Chapter 3: Methods

3.1 The scope of the inquiry

The subject of this thesis has grown out of an interest in two related areas: one, the problem of environmental justice and an increasing interest in public participation in environmental policy, and two, the translation of these normative concerns in regulatory debates around exposure to chemicals. In particular, I was interested in those exposures which are likely to be considered as mundane, i.e., those that occur everyday, often with little active recognition or awareness of potential risk. For example, chronic low-level exposure and exposure to mixtures of different chemicals through use of cosmetics and cleaning products (Friends of the Earth, 2002a; Women's Environmental Network, 2004; WWF-UK, 2004) or through the consumption of pesticide treated food (Pesticide Action Network, 1997; Friends of the Earth, 2004b, 2004c).

Preliminary research revealed that although there is a large array of scientific literature on this type of exposure, when the subject was translated into policy documents it was always tied to particular research themes. Given the time and resource limitations of the PhD I decided to adopt a case study approach. Several possible case studies were examined that included biocides, pesticides and phthalates. The case of pesticides was chosen as although synthetic pesticides have been used and regulated in some form since the late 1940s and their presence in food is currently deemed acceptable by bodies such as the Food Standards Agency (Food Standards Agency, 2004b), their use and effects

remain actively debated within the scientific, policy and consumer literature.

Exposure to mixtures of pesticides can occur through a variety of pathways; to consider all or even several of these routes would be too large a task for one PhD thesis. Food residues were chosen as a primary case study as they represent the greatest source of non-occupational exposure to pesticides. It is an area that has become increasingly regulated both at a UK and European level. However, although officially set exposure levels for individual pesticides are seen as acceptable by the regulating bodies, there continues to be concern and debate about potential effects of exposure to multiple pesticides as explained in the previous chapter.

3.2 Research methods

This study uses a combination of interviews and documentary analysis to explore the research questions set out in Chapter One. A qualitative approach to this study was chosen as it permitted a focus on values and allowed the case study to be examined within a broader context of complex power relations. Silverman (2001) stresses the need when using multiple methods to keep things simple, stating one way to achieve this is to limit the amount of data used within the research. I was therefore very careful to have clear objectives from the outset of my fieldwork so as to use my time and resources efficiently and to set clear parameters concerning what would and would not be included.

Documentary analysis of scientific journals, policy and government advisory literature, and NGO campaign literature (including that produced by industry and trade associations) was undertaken to achieve a contextual understanding of the issues and debates surrounding exposure to pesticide residues. Appleton and Cowley (1997) discuss the benefits of documentary analysis stating that official records, documents and media literature "can provide the researcher with a wealth of easily accessible and readily available research data" (Ibid, p.3). However, despite the often easy access, such data are not without limitations. For example, Stewart (1984) expresses doubt regarding the benefit of using secondary data because they are not originally compiled for the purpose of the current research. Like interview data, documentary data is not free from bias. Documents, especially those written for political purposes, are likely to present a particular impression of the author or the organisation that produces them. As such they may be described using Prior's (2008) terminology as "active agents".

Interviews with 25 key actors in the pesticide assessment community were conducted during the second and third year of this PhD in 2007 and 2008. A semi-structured approach that centred on a pre-compiled interview guide was chosen in preference to a more formal approach. Interviews typically lasted between 40 and 120 minutes. Where possible, interviews were recorded and then transcribed. The majority (18) of such meetings were formal occasions being conducted at the interviewees' place of work. However, on two occasions this was not possible and telephone interviews were conducted instead. A number of interviews (5) necessarily had to adopt a less structured approach; for example, being

conducted over lunch or during the course of a longer visit where I had been allowed to *hang out* at my interviewee's work place. In such cases I felt that it would have been both impractical and inappropriate to have recorded the exchanges made during the meeting. Instead, observational notes were written during and after the meetings.

Gudmundsdotter (1996) and Marton (1981) write that a semi-structured interview style allows an interactive flow of information between interviewer and interviewee. I deliberately chose this style, as this approach allowed me flexibility in the questions that I asked. This flexibility allowed my participants to explore themes and issues that they felt to be important and raised many points and further questions that I, as an outsider, may not have been aware of at the beginning of my fieldwork. In this way each interview helped inform and structure the discussion of subsequent interviews.

A more flexible approach also allowed participants to talk about their own discipline, which would have been more difficult to discuss using a very structured approach. In giving my interviewees this freedom I was able to gather data that allowed me to examine how they discuss their own research in relation to others and examine how their description may vary from more formal accounts of their work. In doing so I was able to map the boundaries, as drawn by them, in a manner that I would not have been able to achieve had I entered with a priori assumptions.

3.3 Sampling and access

It is acknowledged by Becker (1998 p.67) that sampling is a major issue for all researchers and that it is impossible to study every relevant case. In recognition of this a purposive sampling technique was applied to answer the research questions. While there is a continuing debate among qualitative researchers about the need for generalisability in research, this method was deemed most suitable in this study as it allowed the researcher to target specific actors who were most relevant to the research questions posed. Hammersley (1992) emphasises that the decision against the use of probability methods does not always preclude the researcher from making "reasonable judgements about the representativeness of findings drawn from a particular setting to some wider populations" (Ibid, p.88). However, he is equally clear that when using such methods, empirical generalisations can only be achieved if the studied population to which findings may be generalised is adequately defined. In this study, the main aim is to understand how the wider changes identified in scientific advice and chemical risk assessment affects the specific case in question. In this respect, generalising to a wider population is not really the main concern. Having said this, findings from this case study might be expected to contribute to a wider assessment of how chemical mixtures are managed across different domains or on the impact of formal changes in the organization of scientific advice on practice in different committees.

3.31 Documentary data sources

During the first year of my PhD I began reviewing the Science and Technology Studies (STS) and sociological literature, the output of which is shown in Chapter Two of this thesis. By conducting this review I was able to place my research within a wider body of academic literature that has previously explored and theorised about the issues I planned to examine in this PhD, namely the relationship between science and policy, notions of expertise and engagement and the scientific, social and political treatment of risk and uncertainty in the creation of public risk advice.

In parallel to the review of the sociological and STS literature I examined the scientific literature surrounding toxicological and pesticide risk assessment studies, specifically that relating to the study of the effects of exposure to low-levels and mixtures. This literature was largely obtained through using journal search engines such as Web of Science, using key words and phrases such as: 'pesticide*' and 'risk*', "regulatory risk assessment", "pesticide toxicology", "pesticide mixture*", 'pesticide*' and 'synerg*'. Key relevant scientific journals were also regularly reviewed, such journals include: Toxicology, Toxicological Sciences, Journal of Toxicology and Environmental Health, Food and Chemical Toxicology, and Environmental Health Perspectives.

Through grounding myself in this body of literature I was able to develop what Collins and Evans (2002) describe as *interactional* expertise, i.e., I became knowledgeable and competent enough to participate in technical discussions and interact with those working in the area of risk

assessment. This knowledge and awareness of the literature helped to ensure that I was perceived as a credible researcher during my interaction with those I was studying.

In particular, reviewing this very technical literature allowed me to gain a greater understanding of the science underlying my research questions and explore how those working within the area understood and conceptualised the challenges and uncertainties present, or ascertain whether they were even recognised or discussed and by whom. Undertaking a review of both the social and scientific literature therefore not only helped to situate my own research within the wider field, but helped structure the design of my research including shaping my methodology and informing the interim research hypotheses and questions I compiled prior to my interviews.

In addition, to further accompany and inform my interviews a number of official documents and public advice literature produced by UK and European advisory bodies and NGOs (both campaign groups and industry) were also analysed to understand how risk and uncertainty in pesticide risk assessment was understood more widely. Specifically, I was interested in the advisory literature produced by the Pesticide Safety Directorate (PSD), the Advisory Committee on Pesticides (ACP), the Royal Commission on Environmental Pollution (RCEP) and the two working groups of the Food Standard Agency's Committee on Toxicity; WiGRAMP and the VUT. In general, the public nature of this information has meant that these data have been relatively easy to access.

Despite many of the advisory documents being held in the public domain I experienced several problems in obtaining documents from both the FSA and the RCEP. I was particularly interested in reviewing the material that related to the discussions held by WiGRAMP; this advisory group no longer operates and published its final report in September 2002. Hilgartner (2000), in his writing on the performative function of scientific advice, states that a report cannot reveal the internal dynamics of a committee, nor can it provide any information on what aspects of the report were altered or discarded before publication, or show which claims were controversial and which were uncontested. In considering the above I was therefore interested to see how much the final report resembled the draft that was produced earlier in 2002.

In relation to this I made several requests to see the comments that were submitted to the Working Group following the publication of its draft report. Although under the Freedom of Information Act I am entitled to see this information, each of my applications was denied. I was first advised that this would not be possible as they were confidential; when I questioned this I was advised that the documents had been misplaced and that no one in the department could locate them. I tried a further time but again was refused permission, being told that they are probably centrally stored and would be too difficult to access. As a last resort I broached the subject during an interview with a senior manager at the FSA; I was assured that they would try and locate them, however, when the draft report was forwarded to me it transpired that it was actually a draft copy of the final report before it was published. To mitigate this problem I contacted several of those who were listed as submitting

evidence or correspondence to WiGRAMP and asked them directly for their submission. In the majority of cases those contacted provided me with the requested information.

To answer my first research question - *How have the potential risks of pesticides been historically assessed and regulated in England and Wales since their first commercial use in the mid-twentieth century*? - it was necessary to undertake archival work at the National Archives to explore how the assessment of pesticides has been conceptualised and managed within the UK Government and its scientific advisory committees over the last half century. While such information can at times be rich in historical detail it can also be patchy, leaving the researcher to interpret and sketch around the data which have survived and been recorded. In this sense, similar to other more current documents, archival evidence does not tell a full story. However, the archival evidence was often found to contain internal correspondence that was personal in nature, frequently outlining internal government disputes at a level of detail not present in the readily available information provided today by government bodies in a bid to be more transparent.

3.32 Interviewees

The interviewees in this study were chosen following documentary research in the first year of the PhD on the area of pesticide risk assessment and regulation. This research enabled me to create a map of the key actors within this field. The creation of a physical diagram allowed me to draw links between agencies and actors, which in turn helped me

to highlight the key figures in this field. This method was particularly helpful as the actors in this field form a tight knit community with many actors playing multiple roles. For example, over half of my interviewees have served on several advisory committees in addition to maintaining their academic career; several are also linked with the chemical industry or environmental NGOs. In this sense they are difficult to adequately categorise into discrete study populations and any attempt to do so would be largely artificial. However, the practical necessity of discussing this research required me to apply some form of categorisation to my interviewees. Interviewees are therefore identified only by the group that they were interviewed in relation to e.g. member of the Advisory Committee of Pesticides; to list their multiple roles would act to further reduce their anonymity. Interviewees are also labelled according to whether they are current or former members of such groups – a full list of interviewees can be found in the Appendix. It is recognised that advisory committee membership frequently changes, so that those members described as current in the period of interviewing (2006-2007) may not be members in 2009 when this thesis was submitted. These findings mirror those of Desmond (2004), who describes her interviewees as a "hybrid elite". The term refers to the fact that her interviewees, who all worked within Ireland's Biotechnology sector, often straddled multiple domains that included science, industry, policy and activism (Ibid, p.263).

The research is interested in how scientific uncertainty is understood and managed in the creation of advice regarding exposure to pesticide residues in food. I was therefore interested in interviewing actors who are actively involved in reviewing scientific literature to produce public and

policy advice, thus I concentrated on interviewing members of three UK advisory committees that have recently debated such issues. The first was the Advisory Committee on Pesticides (ACP), a government scientific advisory committee, where members are drawn from outside of the civil service. The ACP is charged with providing advice to Ministers and regulatory departments on matters relating to the control of agricultural pests and falls under the auspices of the Pesticide Safety Directorate (PSD). The other two were working groups of the Food Standard Agency's Committee on Toxicity (COT): The Working Group on the Risk Assessment of Mixtures of Pesticides and Veterinary Medicines (WiGRAMP) and the Working Group on Variability and Uncertainty in Toxicology (VUT) – as these groups are relatively small, these interviewees are referred to as COT members throughout this thesis to limit the possibility of identification. Eleven of my interviewees had sat on one or more of these groups and two more had acted as scientific advisors to these groups. I specifically focussed on toxicologists but also interviewed scientists from other disciplines relevant to human risk assessment such as epidemiology and endocrinology. I became aware during my fieldwork that members of these groups often had conflicting opinions and often approached the discussion from differing philosophical standpoints. I was therefore keen to reflect this in my interview data.

I initially approached my intended interviewees through a formal letter or email that briefly detailed my research and asked for their participation. In general I had a very high success rate, with the majority of those contacted agreeing to participate. However, there were a number of instances where I experienced problems. While it was relatively easy to

gain access to those who work in academia and/or those who have sat on advisory panels, I experienced several problems accessing representatives from the agrichemical industry and NGOs working in this field. These difficulties arose for a number of reasons. After contacting several large chemical companies I was informed that they were unable to speak with me on the grounds of trade confidentiality. I also experienced difficulties in arranging conversations with several NGO groups; a common factor being a lack of staff and resources and the fact that many were no longer working on this issue and so were reluctant to discuss it. To mitigate this I have utilised publicly available documents to elicit their position on the matter.

To put the above into context, six out of ten WiGRAMP members were contacted; three participated and three declined, the two lay members were not contactable, of the remaining two, one works abroad and one was not deemed relevant due to their research interests. Six of the twelve VUT members were contacted and five participated. Of the remaining six; the two consumer representatives could not be contacted, one member works abroad and four held research interests beyond that of my study. In 2006 there were 19 members of the ACP; however, this number includes experts on both the human and environmental effects of pesticide exposure and two lay members. For the purpose of this research I needed to focus on those working in human risk assessment. I therefore conducted five interviews with current members, which included one lay member, and a further two with past members who had held senior positions within the committee. The majority of those who had participated held permanent academic positions within a UK Higher

Education institution, the remainder were either employed as professional scientists or had recently retired.

To complement those mentioned above, I interviewed several other toxicologists and risk assessors who are not directly involved in the advisory process. These interviewees tended to work in the more developing and experimental areas of toxicology and included; one of the UK's leading mixtures toxicologists, a computational toxicologist and a probabilistic modeller. Although useful in providing context to this research, much of the data collected from these interviews were not relevant to the main focus of this thesis regarding how those within the advisory process were treating this type of research.

I discovered during the course of my fieldwork that there was a tension between the ACP and Royal Commission on Environmental Pollution (RCEP) regarding the selection and interpretation of scientific evidence when creating advice regarding exposure to pesticides. While the RCEP's focus was on the effects of pesticides on bystanders from crop spraying, and not through the consumption of food residues, there is an overlap in the literature that is discussed. I therefore interviewed a former senior member of the RCEP who participated in the 2005 report on "Crop Spraying and the Health of Residents and Bystanders" (Royal Commission on Environmental Pollution, 2005). I had initially contacted the chairman of the UK Pesticide Residues Committee (PRC), which also falls under the PSD. However, my invitation was declined. I decided against interviewing other members as the PRC is primarily concerned with the monitoring of pesticide residue levels on crops as opposed to the review of risk

assessment data and the setting of limits, which is undertaken by the ACP. In this sense the PRC are acting at a level beyond the interest of this thesis.

Six additional interviews were conducted with representatives from both campaign groups and industry trade associations. Lastly, three senior members from the FSA and PSD were interviewed to discuss the policy implications of unresolved scientific uncertainty and how evidence and expertise is used in the production of risk advice.

3.33 Interviewing elites

Many of those I interviewed can be thought of as occupying *'elite'* positions. Here, I use Lilleker's (2003 p.207) definition of elites as those "with close proximity to power or policymaking". He suggests that through interviewing such a group the researcher has the opportunity to learn about events that occur "behind closed doors" and gain insider knowledge regarding the influence of and relationship between actors working within policy decision networks. While Lilleker focuses on elites found within the political sphere, the term can equally be applied to those working within the scientific advisory community. In his study of the connections between the academic scientific research community and wider society Mulkay (1976) argues that the scientific elite act as mediators of scientific knowledge. He highlights that after World War II the role of the scientific elite as policy advisors has become institutionalised in both the UK and the US, with the result that the elite now act as the link between academia, government and wider society. It

is therefore important to first identify the elite working within the area of pesticide regulation and ask what influence they have on the production and use of scientific knowledge.

Odendahl and Shaw (2002 p.304) highlight that the key themes when interviewing elites are accessibility, control and power. While the majority of my interviewees proved easy to contact, difficulties arose in contacting those who had retired from public life; I was often met with suspicion by past work colleagues and I was frequently vetted for my suitability by past secretaries and admin staff. Many of my interviewees conduct research involving *in vivo* methodology and were at first reluctant to speak with me until I told them exactly what I wanted to discuss, as they were wary of animal rights campaigners.

Invariably, I travelled to my interviewees' workplace and like others "researching up" was often made aware of my interviewees' elite position. During the course of my interviewing I experienced all the subtle power dynamics that are discussed by Odendahl and Shaw (2002). For example, being kept waiting, often with no explanation given; having the interviewee take telephone calls during my visit; having the interviewee switch topic or ask questions regarding other interviewees. Additionally, many of my interviewees, although not social scientists, often took it upon themselves to tell me how I should be conducting my research.

Several of my participants confided that they had children the same age as me, many of whom were also in university education and undertaking a PhD. They would therefore engage me in conversation about post-

graduate education and my student lifestyle. In that sense I often felt the relationship to be almost paternal and I was looked upon like they would a friend of their child. This often manifested itself in what I would describe as parental concern with them trying to be helpful towards me, not only during the interview but also in checking that I would be fine on my return journey, did I need help getting to the station, whether I had managed to get lunch, how was I coping with my studies and so on. Desmond (2004) states that when asked similar questions she felt belittled. However, I took these concerns in the spirit in which I believe them to be intended and used it as an opportunity to build a rapport with the interviewee, in case future contact would be required. Indeed, I found it was helpful for this type of relationship to be created as I then became unthreatening, which often resulted in candid interviews.

Another important tool that I was able to use to build rapport and gain confidence was to *let slip* early in the interview that I had a scientific background. Many of my interviewees were quite scathing of social scientists, suggesting that they do not understand “real science” or the pressures faced by scientists; this attitude was especially prevalent when the use of animals in tests were discussed. By telling them that I had previously undertaken a scientific degree I was no longer an outsider with whom they had to be careful, but a paid up member of their club. The fact that my science degree only marginally overlapped with the area I am studying was also beneficial. This overlap allowed me to sound knowledgeable about some aspects of what we were discussing but also allowed me to *play dumb* on others. Although a slightly deceptive tactic,

this was useful as it allowed me to ask questions at a quite basic level without undermining my position as a competent researcher.

3.4 Ethics

It is imperative when conducting any social research to consider the subject of ethics. While this research did not have to be formally assessed by an appointed ethics board, the issue was considered at some length. Practical advice on how to best achieve this was sought and I applied principles as suggested by Mason (1996). These included informing potential participants of the nature of the study when they were initially contacted and asked to participate. Additionally, all participants were formally thanked through written correspondence shortly after the meeting. At the beginning of each interview I requested permission from the participant to record the interaction and explained that it would be transcribed and may be used not only in my PhD research but also as a resource for future papers or other work produced by myself. The participants were advised that the data would be treated as confidential and that they would, unless they specifically requested otherwise, be anonymised in the thesis and all other work produced. I have tried as a principle to omit any identifying features of the interviewees through the use of false names and identities as is suggested by Wind *et al.* (2004). However, I recognise that the field from which my interviewees were chosen is small. Therefore it will be relatively easy for those within that community to attribute particular viewpoints to specific individuals. However, the majority of my interviewees hold prominent positions within

their field and so many of their opinions are likely to already be in the public domain.

During my research I was given information that was particularly sensitive, for example, information regarding advisory discussions that have not been made public or regarding personal relationships between interviewees. On occasions I was asked to turn off my recorder and to treat the information as *"off record"*. The information gathered while the recorder was turned off has not been used within this thesis. Other interviewees asked not to have particular views attributed to them, in such cases I have tried to further anonymise their comments through simply labelling them as a committee member.

As a rule I did not disclose interviewee identities to other interviewees. However, on some occasions it was necessary to reveal that I had spoken to certain people, and in cases where I was introduced to new interviewees through past contacts this disclosure was unavoidable. Several of my interviewees also discussed the work and opinions of other academics and fellow advisory board members, many of whom I had, or intended to interview. This is perhaps unsurprising given that this area is dominated by a relatively small group of people who appear to know each other on both a personal and professional basis. Such cross referencing of other elites and the highlighting of elites as being part of a wider social and political network is also noted as a feature of this type of research by Desmond (2004) and Cormode and Hughes (1999).

Where, during interviews it was necessary to discuss other people's work or opinions, I was careful to only discuss information that was publicly available, and did not attribute information obtained through previous interviews to individuals. Murphy and Dingwall (2001) cite Borland (1991) and Stacy (1991) to highlight that participants, when reviewing information that they have provided, may be unhappy at how they have been depicted or may not recognise their story as their own. Several of my interviewees requested that if I were to publish my research that they are shown any material that I would be attributing to them, even when anonymised. I believe this to be a reasonable request as the issue of pesticide residues remains contentious within the media with many of my interviewees unhappy at how the issue and their work is portrayed. Murphy and Dingwall (2001) use Cassell's (1978) work to illustrate that once information is made public it is difficult to control how it may be used or viewed in the future. I therefore believe it is the researcher's responsibility to record and present field data in an accurate and factual manner so as to try and avoid any misinterpretation that may be damaging to those who participated in your research. This work has not yet been formally published but I plan to adhere to the requests that were agreed between me and my participants during the publication process.

3.5 Data analysis

The interview recordings were transcribed and analysed thematically, with each separate theme coded and broken down into sub-themes. Coding was done manually and without the use of data management software

such as NVivo. I decided against the use of such software as I felt it would distance me from the raw data and present a fragmented picture, where themes would appear artificially discrete. Through using manual methods I was able to gain a more holistic understanding of the data and observe often complex links between different themes.

Key themes that were found across the data were ideas of boundaries, whether between science and non-science or expertise and non-expertise, and the importance of framing in both conceptualising and solving problems. To analyse the data I therefore drew on existing literature from Sociology and Science and Technology Studies (STS) that have explored these concepts in other settings. A description of these concepts and justification of their use can be found below.

3.51 Boundary work

The issue of demarcating science from non-science has been widely discussed within the STS literature and is relevant to this work, which seeks to understand why certain evidence and expertise is considered as more acceptable than others in the risk assessment of pesticides. The specific term “boundary work” was first used by Gieryn (1983) to highlight how scientists distinguish their work from non-science through:

> Their attribution of selected characteristics to the institution of science (i.e. to its practitioners, methods, stock of knowledge, values and work organisation) for the purpose of constructing

> a social boundary that distinguishes some intellectual activity as non-science. (Gieryn, 1983 p.782)

Gieryn (1983) argues that boundary work routinely occurs at all levels of scientific discussion ranging from the teaching of science in the school to the direction of research of national funding councils. In making this claim he stresses that demarcation is not simply an abstract issue for the debate of social scientists. Instead, its use can tangibly affect not only the material resources made available to actor groups but also lead to the reinforcing of professional authority and privileges among those perceived as '*scientific*'.

In drawing on the work of the philosopher Thoreau, Gieryn (1999) later likens boundary work to the process of map drawing, proposing the term "cultural cartography" to illustrate how epistemic authority and credible methods are drawn out to create borders and landmarks on a cultural map to signify what is and is not science. It is important to note that such landmarks and boundaries are not static or drawn objectively; rather they are contextual and differ depending on the cartographer and purpose of the map. Boundary work can therefore be viewed as a strategic behaviour employed by scientists to protect the boundaries of their discipline and social community from threats against its cognitive authority (Guston, 2001).

Halffman and Hoppe (2002) using the work of historian Steve Shapin (1992) build on Gieryn's research to suggest a wider definition of boundary work:

> Boundary work defines a practice in contrast to other practices, protects it from unwanted participants and interference, while attempting to prescribe proper ways of behaviour for participants and non-participants (demarcation); at the same time, boundary work defines proper ways for interaction between these practices and makes such interaction possible and conceivable (coordination). (Halffman and Hoppe, 2002 p.13)

Boundary work can therefore be seen as dual purpose, where demarcation is used to distinguish between groups and coordination is used to examine how apparently rival groups relate to one another.

So far, boundary work has been discussed as a deliberative strategic action. However, other researchers, while agreeing that boundary work routinely occurs, make the suggestion that such practices are often applied unreflectively within everyday practice often acting to reinforce existing organisational attitudes (Knorr-Cetina, 1981; Kinchy and Kleinman, 2003). In extending these assumptions in their own empirical research, Eden *et al.* (2006) show how boundaries are contingently drawn, resulting in a fuzzy grey area of negotiation and rhetoric. They highlight Jasanoff's (1987) research on the blurring of boundaries between science and politics to illustrate how 'science' can be a pliable resource used to further a rhetorical case or suit the needs of the cartographer. Guston (2001) too highlights Jasanoff's (1990) work, but uses it as an example of how boundary work can be policy-relevant with the blurring of boundaries resulting in more productive policy-making.

Both Gieryn (1999) and Halffman and Hoppe (2002) argue against essentialism; if there is no fixed definition of science or politics then there can be no one right way to demarcate between the two. This issue is further complicated by the heterogeneous nature of science and the differing frameworks found within different scientific disciplines. Halffman and Hoppe (2002, p.11) therefore use Gieryn's definition of boundary work to provide a framework for social researchers to study this strategic action. It is this framework (shown below) that I have used in this research:

- Analyse how the actors involved define science.
- Discover what they consider to be scientific and non-scientific practices, problems, tools, theories, conceptions, behaviour or people.
- Analyse how such conceptions are presented discursively as strategic moves to claim or deny legitimacy in areas of social life.

Indeed, it has previously been suggested by Barnes (1974) that that before we as academics attempt to define and demarcate science we should examine it as it is defined by the actors under study. Hence, I have used the concept of boundary work not to make claims over the scientific basis of the data used to formulate risk advice, but as a tool to explore and understand how the actors involved map out the boundaries of what they believe to be scientific and who they consider expert, and to explore the consequences of such cartographic creativity.

The concept of boundary work has been usefully extended to consider “boundary objects” (Star and Griesemer, 1989) and “boundary-ordering devices” (Shackley and Wynne, 1996). In recognising the heterogeneity of science and the different view points, and thus tensions that this brings, Star and Griesemer (1989, p.393) suggest a new analytical concept – boundary objects, which they define as follow:

> Boundary objects are objects which are both plastic enough to adapt to local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites. They are weakly structured in common use, and become strongly structured in individual-site use. They may be abstract or concrete. They have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable means of translation. The creation and management of boundary objects is key in developing and maintaining coherence across intersecting social worlds.

Shackley and Wynne (1996) have built on this concept to suggest that within scientific debates scientific uncertainty can challenge both the science and the authority of scientists. Scientists therefore often have to occupy a dual position in order to retain a technical rationality when involved in policy making processes; on one hand they are obliged to acknowledge and discuss uncertainty, while on the other they have to minimise the follow-on assumption that uncertainty challenges the authority of science, making it unsuitable for use in policy making. This

may create an additional tension in the field of risk assessment where there is often a cultural desire (as discussed in Chapter Two) to reduce the incidence of Type 1 errors (false-positives) so as to avoid over-regulation. In this sense scientific uncertainty is used as a boundary-ordering device that "allows scientists (i) to translate uncertainty for policymakers so as to make its reduction appear more tractable and (ii) to maintain a richer, or more heterogeneous, version of uncertainty for scientific communities than for policymakers so that scientific integrity can be preserved around an agenda of tractable scientific problems" (Shackley and Wynne, 1996, p.293; Barke, 2009). These concepts will be used to help consider how the actors involved in the risk assessment of pesticides manage scientific uncertainty.

3.52 Framing

In situations where questions and problems associated with risk are difficult to single out from a melange of inter-connected issues it often becomes necessary to invoke a selective vision, where issues are *framed* to make them manageable or controllable. According to Goffman (1974, p.21) framing allows actors to "to locate, perceive, identify, and label" problems. Framing therefore provides meaning and a method by which actors can organise and guide future action (Koenig, 2007). The development and invocation of regulation can therefore be viewed as one method of framing.

Accordingly, frames are used by actors as "principles of selection, emphasis and presentation composed of little tacit knowledge about what

exists, what happens, and what matters" (Gitlin, 1980, p.6). While in many instances framing may be latent, others have argued that framing can be a deliberative and manufactured process allowing actors to focus attention on and promote one problem definition or recommendation over another (Entman, 1993).

Once problems have been framed it follows that they should become easier to solve. Thus, complex problems may be tamed for the purpose of constructive discussion or regulatory ease. However, it must equally be recognised that any solution to a tamed problem is unlikely to account for those wild issues that have been excluded from the problem and subsequent discussion (Jasanoff, 2000; Millstone, 2007).

Millstone (2007), drawing on Sheila Jasanoff and Brian Wynne, has argued that the institutional and political contexts in which advisors work can strongly shape their "framing assumptions". Millstone (ibid, p.499) suggests these assumptions are important for four reasons:

> Firstly, they are very influential, secondly, they have exercised their influence in an almost entirely invisible or unacknowledged way, thirdly, they are readily contestable, and fourthly, because the unacknowledged ways in which science and politics have been hybridized, and then misrepresented as if purely scientific, have been fundamental failures, of which BSE and GM crops are two of the most conspicuous examples. (Millstone, 2007, p.499)

Thus, framing can be used to determine what evidence is and is not allowable in risk discussions and how such evidence is interpreted. A key consequence may be that those who are not able to present acceptable evidence are effectively excluded from actively participating in any risk dialogue, a situation at odds with the current UK Government goal of wider engagement. In the same vein, where there are alternative framings of the same issue there is the potential for miscommunication and a greater likelihood of disagreement in proposed solutions or advice.

The concept of framing will be used in this thesis to explore how different groups conceptualise the issues surrounding the risk assessment pesticides and the production of risk advice and which actors are allowed to participate in these debates.

3.6 Summary

In this chapter I have provided a detailed overview of the methods used within this research - documentary analysis and interviews – detailing the reasons behind these choices.

Specifically, I have discussed issues surrounding sampling and access, ethics and the difficulties in interviewing elites and obtaining grey literature. Here, I detailed that 25 interviews were conducted as part of this research and that interviewees were largely those working within the pesticide advisory system, although, a number (6) were members of NGOs or industry groups. I discussed that the majority of the

documentary evidence was relatively easy to access and where there were problems, alternative evidence sources were considered.

Lastly, I have discussed how the collected data have been analysed using a thematic approach that has drawn on the concept of framing and boundary work.

Chapter 4: History of Pesticide Regulation in England and Wales

4.1 Introduction

There are currently few detailed historical narratives that explore, using archival data, how pesticide assessment and use have traditionally been managed in England and Wales[15]. In this chapter I therefore aim to address the first of my research questions - *How have the potential risks of pesticides been historically assessed and regulated in England and Wales since their first commercial use in the mid-twentieth century?* - to understand how historical decisions may have shaped pesticide assessment and regulation as we understand it today.

To achieve this I will detail how statutory regulation has evolved through a succession of voluntary agreements. In particular, I focus on the beginnings of English pesticide assessment and regulation in the 1950s and 1960s, illustrating how decisions made during this early period have directly shaped the role and remit of current English pesticide advisory bodies. I show that from the 1950s onwards there were serious concerns raised relating to chronic exposure to low-levels and exposure to mixtures of pesticides. However, I argue that the archival evidence suggests that such concerns have been persistently bracketed within the assessment

[15] Notable exceptions are van Zwanenberg's (1996) PhD thesis on "Science, Pesticide Policy and Public Health: Ethylene Bisdithiocarbamate Regulation in the UK and USA", and Gilbert's (1987) PhD thesis on "Pesticide Safety Policy and Control Arrangements in Britain".

and regulatory process, and thus effectively removed from the remit of pesticide advisory bodies.

I conclude the chapter with an overview of the process currently used to determine Maximum Residue Levels (MRLs) for pesticides and discuss the UK's regulatory integration within Europe.

The assessment of pesticides falls over several regulatory areas depending on their type, use and potential hazard. This thesis is largely concerned with the risk presented to the public through the consumption of food containing residues. In the following account of English regulatory history I therefore concentrate on the regulation relevant to consumer protection. However, some issues relating to other regulatory areas, such as operator and bystander safety or effects to wildlife, provide the wider context to this discussion and convey the complexity of pathways of pesticide exposure that inevitably overstep the socially constructed boundaries of regulation.

Much of the information used within this chapter has been obtained through the examination of archival data which is supplemented by case studies; this was previously discussed in Chapter Three.

4.2 1900-1950: Assessment to ensure efficacy

The application of pesticidal substances to plants can be traced back through written records to Homer in 1000 BC (Carlile, 2006). However, although there are sporadic records of chemical preparations being used

for pest control purposes throughout history it is not until the mid 20th Century that pesticides were adopted for use on an industrial scale (Ware and Whitacre, 2004). Until the 1940s pesticides were largely inorganic chemical preparations that were primed for use prior to application; this 'homemade' status meant there were few official rules and regulations surrounding their safe use (Russell, 2005).

The beginnings of English pesticide regulation can be traced back to 1931 when the Ministry of Agriculture and Food (MAF), apparently under pressure from the National Farmers Union, suggested to the Association of British Insecticide Manufacturers (ABIM[16]) that traders of pesticides should label their preparations and submit these to government. Pesticidal substances could then be put on an approved list with the aim of helping farmers reduce their outlay on inefficient products (van Zwanenberg, 1996). It was also during this period that MAF began to conduct annual surveys of crop diseases throughout England and Wales (Russell, 2005).

In 1942, the Advisory Committee on the Scheme for Approval of Proprietary Products for the Control of Plant Pests and Diseases was established. The purpose of this committee was to consider applications made voluntarily by pesticide manufacturers; applications were assessed on factors such as safety, product labelling and proposed use. Following amendments to the scheme, the title of the scheme was altered in 1949 to the Crop Protection Products Approval Scheme (CPPAS), which was superseded in 1960 by the Agricultural Chemicals Approval Scheme (MAF

[16] ABIM is now the Crop Protection Agency.

371). The CPPAS was designed to enable professionals to provide advice on crop protection products, with accepted products allowed to label themselves as Ministry approved (MAF 98/484). The statement below suggests that at this time applications were assessed on the basis of efficacy as opposed to safety, with members encouraged to approve substances “wherever possible”:

> Although the attitude of the Advisory Committee to its work is to recommend the approval of products wherever possible rather than their rejection, the scheme will have the effect of discouraging the use of unsatisfactory preparations. (MAF 98/484, PS37: 2)

The Committee argued that in order for the scheme to operate, the Advisory Committee required a Joint Panel which could provide it with the necessary guidance. In addition to members of the Advisory Committee and representatives of other government departments, the Joint Panel included five representatives of the ABIM (MAF 98/484, PS 37: 3). The inclusion of the ABIM on the Panel suggests that there has historically been a close working relationship between government and industry in the area of pesticide regulation. Such a relationship is likely to have been beneficial to pesticide manufacturers as not only would they have had representation within the approval process but they would also have gained a valuable insight into how products came to be recommended or rejected.

An important breakthrough in the development of commercial pesticides came in 1938 and 1939 when the first organophosphate, TEPP and the organochlorine, DDT were discovered (Hajek, 2004). The chemical properties of DDT were subsequently passed to the British Ministry of Production, whose wartime work led to significant advances in the development of crop protection products (Green, 1995). By the end of the Second World War, the group working on DDT at the Ministry of Production had been disbanded, instead, an inter-departmental committee was established within the Agricultural Research Council (Green, 1995).

To summarise, there appears to be little evidence of any form of pesticide regulation or government involvement in the production and use of pesticides prior to the 1930s. During this period, Ministers and government departments favoured the use of voluntary approval schemes over statutory product registration and encouraged the participation of industry groups within the advisory process. Assessment of pesticides was focussed towards determining efficacy as opposed to safety, which appears a secondary concern during this time.

However, the rapid advances in the chemical industry and its application to crop protection products during the Second World War resulted in the UK Government paying increased attention to ensuring both the efficient and safe use of pesticides, changes that will be discussed in the next section.

4.3 1950-1960: The Working Party on Precautionary Measures against Toxic Chemicals used in Agriculture

Linked to both the increasing availability and use of pesticides was a growing concern for the safety of agricultural operators. During the 1940s, several deaths and poisonings of agricultural workers were attributed to the use of the pesticide DNOC and other organophosphate insecticides (Gilbert and Macrory, 1989). These incidents, coupled with the public controversy surrounding the presence of nitrogen trichloride in bread flour and its link to seizures in dogs (Silver and Pollock, 1948), culminated in the establishment of the Working Party on Precautionary Measures against Toxic Chemicals used in Agriculture, chaired by the now eminent Lord (then Professor) Solly Zuckerman. The Working Party conducted three key inquiries under Zuckerman which broadly fell within the following areas: operator safety, consumer goods safety and the effects of pesticides on wildlife.

4.31 1st Working Party Report: Operator Safety

The 1951 report entitled “Operator Safety” highlighted that operators often took insufficient precaution when handling and using pesticidal products. In response to these findings, the Working Party made the recommendation that legal requirements be introduced in respect to the wearing of protective clothing and the safe handling and use of pesticides (Gilbert and Macrory, 1989). These concerns were formally addressed in the 1952 Agriculture (Poisonous Substances) Act, which required the provision of protective clothing for workers to reduce the likelihood of

agricultural poisoning (HMSO, 1952). This Act was enforced by Area and County MAF officials and was largely considered at the time to be successful, if a little over protective (Edson, 1958).

In particular, the Report made explicit reference to the risks involved in the handling and use of organophosphate (OP) chemicals in agriculture. The Working Party, having investigated the health effects of dinitro and organo-phosphorus sprays on workers, concluded that not only should products be better labelled (as a deadly poison) but that there was, at that time, no protective equipment available that would allow both the necessary bodily ventilation and complete protection from chemical exposure. However, the key finding of the report, which is now much cited due to its stark warnings (Lean and Emmett, 1996), was that the chief danger of OP pesticides lay in repeated low-level exposure, which the Working Party felt could result in adverse chronic effects to human health (Hansard, 1996).

During 1951, the Advisory Council on Science Policy also expressed concern regarding consumer safety following exposure to pesticides in food. Gilbert and Macrory (1989) note that although the Advisory Council believed the risk to be small it was concerned that the rapid adoption of new substances posed dangers “for which assessment procedures were inadequate”, especially in respect to the assessment of chronic effects. In response to these fears, the Advisory Council established the Committee on Toxic Substances in Consumer Goods. The Committee subsequently recommended that pesticide manufacturers should submit evidence to the relevant government department to demonstrate that a product did not

pose risks of acute toxicity (Tizard, 1951). Interestingly, despite previous concerns, these recommendations did not cover chronic toxic effects.

4.32 2nd Working Party Report: Effects on the Consumer

Following the above recommendations, the second Zuckerman inquiry focussed on the possible risks of pesticide exposure to food consumers. The 1953 report suggests that the public had become fearful of pesticides as a result of their increased use and a perceived lack of knowledge regarding their toxic effects (MAF 98/484) – strikingly, these same concerns are still present today (Friends of the Earth, 2004a; Pesticide Action Network, 2004). It is noteworthy that at the inaugural meeting of the Pesticide Group in 1954 the discussion centred on the safety of pesticides to the public and environment (Green, 1995), suggesting that this issue was considered pertinent among the UK's leading pesticide scientists at this time.

The first meeting of the Working Party on Precautionary Measures against Toxic Chemicals used in Agriculture (Part II: Effects on the Consumer) was held on 24th May 1951. During this meeting the terms of reference were set out and the list of chemicals that would need to be considered in relation to consumer food risk discussed. Most notably, the minutes of the meeting reveal that "chemicals would have to be judged in the light of present knowledge as there was no time for detailed scientific investigation", an issue that is repeatedly made reference to throughout future meetings (MAF130/61, [WPC (2) 3]). During the second meeting in

July 1951, the Group decided that a Sub-Committee should be enacted to consider the substances in three categories of knowledge that ranged from “unknown toxicity” to “fairly safe”. By the fifth meeting in June 1952, the Working Party had drawn the following conclusions, as are shown in the minutes (MAF130/61). I have highlighted the statements salient to this thesis:

- The **continued use of toxic chemicals appeared to be necessary** to achieve maximum agricultural production and prevent undue losses of stored food.

- That there was little risk to the consumers of food which had been treated with toxic chemicals either in growth or in storage, provided that these substances were properly used.

- However, there appeared to be a considerable risk associated with the improper use of those toxic substances and it had been established that misuse did frequently occur.

- Only 40% of our food supply was home grown and, therefore, able to be bought under direct control. Of the other **60% imported from overseas, little was known of methods of treatment or of the chemicals used**. Moreover, it should be emphasised that there was no control from the retail stage onwards.

- **It was impossible to assess toxicological hazards with any degree of accuracy**; therefore, any decision about control of toxic chemicals must be based on a reasonable assessment of the risk by those who were competent to advise on the information available.

- The existing law (Food and Drugs Act, 1938) already imposed an obligation upon food manufacturers to ensure that the food produced for human consumption was non-toxic.

- **The insecticide manufacturers** already took every precaution to assure themselves that no dangerous risk from residues attended the use of substances which they marketed. They **had expressed a willingness to transform what was now a voluntary undertaking into a statutory responsibility**. By doing so they not only fulfilled their formal obligation under the law, but also strengthened their trading position.

- It appeared advisable to increase and disseminate the knowledge available about toxic chemicals by:-
    - devising further methods of analysis;
    - distributing the available information on those methods and on the known acute and chronic toxicological risk;
    - carrying out further research towards improving existing methods and devising new methods for the identification of residues, especially where break-down products might be involved.

- **More research into the development of safer alternatives** for some of the toxic substances at present in use seemed to be desirable.
    - That in considering whether the continued use of any toxic substance was justified, a balance must be struck between its risk and efficacy and those of possible alternatives.[17]

[17] In a later document the Scientific Sub-Committee on Poisonous Substances used in Agriculture and Food Storage state that the basis for discrimination is the assumption that both do virtually the same job.

The above conclusions appear somewhat inconsistent suggesting that the Working Party faced several obstacles in fulfilling its remit. For example, it concluded that there "was little risk to the consumers of food which had been treated with toxic chemicals…provided that these substances were properly used", yet it later acknowledged that it was "impossible to assess toxicological hazards with any degree of accuracy". Importantly, it concluded that decisions should only be made by those with the necessary expertise who can be considered competent to advise. However, a common theme running through discussions in the 1950s and into the 1960s was that both actual methods and the resources (including trained staff and laboratories) to perform both toxicological tests and residue analysis were either in too short a supply or simply unavailable[18].

However, it suggests that in practice such discrimination is impractical, if not impossible, as it can take years of use to assess a pesticide's value and there are too many variables to consider. It iterates that the Sub-Committee's function is not to recommend one product over another but to judge whether each product presents a toxic hazard to either the user or consumer and if so how this hazard can be reduced (MAF 98/484, PS 53); a practice that remains today.

[18] In response to the second Working Party Report on consumer risks the ABIM clearly states (MAF 130/62, 21 September 1953): "Few manufacturers have facilities for providing information on toxicity and there are only limited opportunities for seeking the help of consultants."

The minutes from the 3rd meeting of the Scientific Sub-Committee on Poisonous Substances used in Agriculture and Food Storage (06.01.1955) also discuss the level of work required in residue analysis. A Dr Ashworth quotes the example of the insecticide Schradan, revealing that the Joint MAF/ABIM Committee had spent two years attempting (unsuccessfully) to find a method of analysis to detect residues of Schradan and its metabolites in food. It was further suggested that the development of

These limited resources therefore raises the question of how certain the Working Party could have been of the scale of risk facing UK consumers at this time. This difficulty was amplified as 60% of food consumed at that time was imported, with little information on how it was produced or stored; where food was grown within the UK it could not be guaranteed that pesticides were properly used.

Perhaps the most interesting conclusion is that indicating insecticide manufactures “had expressed a willingness to transform what was now a voluntary undertaking into a statutory responsibility” (MAF130/61). Indeed the first recommendation made within the draft report produced in December 1952 stated:

> That Departments should take statutory powers to call for the registration and licensing of all chemicals that are introduced and offered for sale as substances which protect agricultural products from diseases and pests. (MAF130/61, W.P.C. (2) 33, p. 19)

However, the apparent willingness of industry to convert to statutory measures is not seen in other documents and memos from that period, which suggests that both government departments and industry had objections. For example, both the Agricultural Department and the Labour Division stated in its consultation response that in its opinion there was no justification for changing the voluntary regime to a statutory one. The

---

new analytic methods for just one chemical could take two full time workers one or more years (MAF 98/484, (PS24)/SC36).

apparent lack of data to firmly conclude whether there was a danger is used to defend maintaining the status quo:

> It is hard to find any real justification for the change of view in this new report, in which the main theme is that there has as yet been no known instance of illness resulting from eating food previously sprayed with weed killers or insecticides and that the main danger is that there is insufficient information to decide whether there is even a potential danger. (MAF130/61, W.P.C. (2) 38)

Archived documents from this period suggest that industry interests were still heavily promoted within this area. For example, it was felt by some government departments that not only would the scheme be difficult to enforce but that the criteria detailing whether new products should be accepted or rejected were insufficient and that government testing facilities were at that time inadequate and may lead to a "tedious delay to the manufacturer" (MAF130/61, Labour Division, 19 January 1953); many of the consultation responses suggest that both the ABIM and government departments did not want to move away from voluntary measures due to the belief that the introduction of statutory requirements would be unnecessarily obstructive to the working practice of industry. It should be noted that during this period manufacturers were only encouraged to notify if they felt that a chemical was likely to present a toxic risk to health. Thus, voluntary arrangements continued to rely on a mutual trust between industry and government.

Similarly, the minutes of the Working Party's meeting on the 20th May 1953 (MAF 130/62) show that the Board of Trade was concerned that the requirements would delay insecticide development and suggested that any "proposed scheme of notification should have the minimum of restrictive effect on the industry". Likewise, the Ministry of Food stressed the importance of promoting consumer confidence "without hampering the industry". Several other documents also indicate that departments did not see the benefits of statutory notification when: "Generally speaking manufacturers of crop protecting chemicals have a proper sense of responsibility and can be relied upon to take precautions and issue instructions [for use]" (MAF 130/61, Horticulture Branch I, 19 January 1953). Additionally, while other countries, such as the U.S., Germany and Denmark had already implemented a form of statutory control, it was thought unnecessary in the UK by many Ministries because "trade organisations have a highly developed sense of social control by voluntary means" (MAF 130/61, Infestation Control Division).

This reluctance led to the Working Party's recommendation being moved in the published report from (i) to (iii) with the wording altered, at the request of other government departments, to include the phrase "as soon as opportunity offers":

> That general enabling powers should be sought, as soon as opportunity offers, for uses if further experience shows that the making of statutory regulations is necessary to ensure that arrangements on the lines proposed in (ii) above work effectively. (MAF 98/484)

This alteration and the relegation of the recommendation suggest that the Working Party was under pressure to accommodate the demands of Ministers and government departments who did not want to jeopardise their relationship with industry. Notably, as early as 1955 this closeness was publicly questioned in the British Medical Journal by B. S. Platt, a leading Medical Research Council scientist. Platt raised concerns that such a relationship could lead to industry interests being unduly accounted for in the advisory process:

> We have, to recognise in this, the possibility of a conflict of interests in which, the British Medical Journal (1954) remarks, "It is doubtful if the influence of any such reformer [posing as a champion of the individual safety and protector of the public welfare] would ever equal that of a powerful commercial interest anxious to introduce a new material or technique into food production" (MAF 130/62; Platt, 1955, p. 179).

The 2nd Report covers a wide range of aspects relating to consumer risk and sought to establish what effect contamination by agricultural chemicals may have upon the consumer. While the Working Party was not able to discover any specific instances of illnesses occurring as a result of eating treated food, it is stressed that this should not lead to 'complacency'. It further stated that new chemicals intended for agricultural purposes should not be commercially applied until there is adequate information regarding their toxicity. Importantly, the report highlights several areas of uncertainty and potential risks to both humans and wildlife in increasing the use of chemicals in agriculture. Specifically,

it acknowledged the limits of animal models in toxicity testing and highlight that there is insufficient toxicity and residue data for many compounds that were in use; limitations that are still pertinent today as I show in Chapter Five.

A key message in the report, and one that is still widely debated, is the potential risk facing the public from the regular consumption of small amounts of pesticide residues over long periods of time. The Working Party believed that the public was unlikely to be reassured about the possibility of chronic effects just because none were shown in long-term rat studies. This issue was discussed further within the section relating to regulatory administration. Here, the report stated that adverse health effects, as a result of consuming residues, cannot be guaranteed to manifest themselves immediately after consumption and as such it may not be possible to link an illness to the consumption of a particular food item[19]. Importantly, this led the Working Party to conclude that the existing legislation was inadequate to ensure the full protection of public health, a position that is still argued by NGOs today (Pesticide Action Network, 2004).

To summarise, the 2nd Report appears to recommend a precautionary approach towards pesticide use and clearly states that a lack of reported illness should not lead to complacency; chronic exposure to low-levels

[19] A point further expanded upon by Platt (1955, p. 180) in the BMJ was that there is a lack of information surrounding the presence of chemicals in food and that their effect on the human body "may be subtle, insidious and long delayed".

through the consumption of food residues was a regularly noted concern. Despite concluding that there appeared to be little risk to consumers from treated food, both the Report and the Working Party minutes acknowledged that there was often a lack of data available on which to assess the risks posed by a pesticide. It was recommended, and indeed desired by industry, that where such data existed it should only be assessed by those deemed to have the relevant expertise, which in this case were seen to be toxicologists.

While the Working Party was actively in favour of a statutory system, the pressure exerted largely by government departments, and to a lesser extent industry bodies, meant that this recommendation was not enacted. The key reasons cited for continuing the voluntary scheme can be summarised as: concern over the effect of a statutory scheme on the pesticide industry; concern over an inadequate scientific knowledge base upon which to regulate pesticides; concern over a lack of governmental resources required to run a mandatory scheme.

In the final report a continuation of the voluntary scheme was recommended, until it could be demonstrated as inadequate. As in the 1940s the ABIM and other trade organisations remained in close working contact with those making regulatory decisions. The implications were publicly questioned at the time but did not result in any notable changes in working practices.

4.33 Maximum Residue Levels (MRLs): Early discussions

In response to the food safety concerns that had now begun to strongly emerge, as described above, the Working Party Report recommended that a separate committee be established to advise government departments on the following four areas: risks to consumers; the technical information required for product notification; the level of liaison required between official and unofficial agencies; and the setting of maximum residue limits (MAF 98/484). As a result, the Advisory Committee on Poisonous Substances used in Agriculture and Food Storage (now the Advisory Committee on Pesticides or ACP) and a Scientific Sub-Committee were established in 1954 to implement the introduction of what would be known as the Notification of Pesticides Scheme (MAF 130/62; Gilbert and Macrory, 1989). The Committee included both administrative and technical representatives from various government departments. It should also be noted that there was a desire among members to include industry in Committee discussions. It was believed that a range of representatives would be necessary due to the diversity of technical problems that were thought likely to arise in evidence assessment. For example, the Industrial Pest Control Association expressed concerns that the Committee should have the relevant knowledge and expertise, which it saw as being held by toxicologists – a theme that has persisted today and is discussed in more detail in Chapter Seven:

> Trade must be fully assured that questions of toxicology would be settled by toxicologists and not by the general committee who may not have the requisite knowledge…the function of the

> toxicologists was to make certain that every loophole was covered and that nothing was left to chance to go wrong, as that would be extremely unfortunate for both the Ministry and trade. This aspect would be the sole concern of the toxicologists. (MAF 130/62, A:10408 W:3)

Minutes from the Sub-Committee meeting of November 17th 1954 show that the issue of residue limits was discussed in relation to the product Schradan (MAF 98/484, PS 18). While members agreed that in general the setting of "permitted or tolerance limits" was desirable, many opposed this in practice. In the example of Schradan several reasons were cited as to why a limit should not be set: lack of field data; insufficient toxicological data; and a concern that the setting of a limit would lead to increases in use simply because it was government approved. Notably, Dr Barnes, a toxicologist from the Medical Research Council argued that: "It would seem that even when we had adequate data on any one insecticide we would have to take a calculated risk in recommending a permitted level". A Dr Martin also worried that: "We may be forced to adopt a possible limit purely for administrative reasons and that a figure would be set before we had sufficient basic information on which to base such a figure".

The issue pertaining to the lack of information was again raised by the Advisory Committee during its December meeting where it was stated that at that time (1954) "no methods were known at present for estimating small concentrations of chemicals". Additionally, analytic facilities were thought to be inadequate, with neither the Medical or

Agricultural Research Councils, nor the Government Chemists having enough staff to do the necessary work (MAF 98/484, PS 22). However, the minutes also reveal the beginnings of the current practice of linking residue limits to Good Agricultural Practice (GAP); Dr Wright from the Ministry of Food urged that:

> …instructions regarding the application of pesticides should always be accompanied by statements of the permissible limits in the crops as sold to the consumer…no crop should be treated with a pesticide for which a permissible limit could not be laid down (MAF 98/484, PS 22).

Despite these issues the minutes from the fifth meeting in 1955 suggest that decisions surrounding pesticide assessment and safety were often weighted in favour of industry as opposed to the consumer. For example, several members of the Advisory Committee felt there were circumstances where the usual notification process could be over ruled as "sometimes a manufacturer could not reasonably be expected to wait while an item reached the agenda of the Subcommittee". Members were reminded that Industry were submitting data on a voluntary basis and as such the Committee should be as cooperative as possible; to both ensure that manufactures continued to have confidence in the process and to avoid resorting to the implementation of a statutory regime (MAF 98/484, PS 48).

A key issue facing both the Advisory Committee and Sub-Committee in designing the Notification and Clearance Scheme was the desire by

manufacturers for secrecy in registration. A principle of "secret notification" was therefore recommended; here information submitted by industry would initially be viewed by preferably one appointed expert and definitely by no more than three officials, who would personally assess and approve the data within three weeks of its submission (MAF 98/484, PS 84).

In later discussions surrounding the setting of residue limits the Advisory Committee recommended that farming practices be modified to allow for an adequate 'safety' time interval to occur between the spraying and harvesting of crops. It was recommended that such intervals should not be arbitrary but based both on chemical analyses of treated crops and on the results of dietary toxicity tests on animals; data which it stated should accompany the notification documents sent to the Advisory Committee to help establish residue limits. However, unlike other European countries, residue limits remained legally unenforceable (Edson, 1958). This point appears to have caused frustration within some parts of MAFF[20], suggesting that the close relationship between MAF(F) and industry in relation to pesticide assessment was not universally welcomed. For example, M.D.M Franklin (Joint Secretary of the Food Standards Committee), stated that he did not feel that the current set up of the various Advisory Bodies was "best adapted or sufficiently wide in its coverage to secure maximum protection for the consumer". Indeed, in discussing whether statutory limits were practical, he is forthright in expressing his frustration with the Sub-Committee's reluctance to impose

[20] MAF's remit widened to include the Fishery industry (MAFF) in 1956.

limits, again suggesting that assessments were designed in favour of industry rather than consumer protection:

> …my impression is that the difficulties are by no means insuperable and that, on the analytical side, the Scientific Sub-Committee may be setting a standard of perfection which is out of line with those we have accepted in other spheres. In any event, it is difficult to see why we cannot make a start when the Americans, who are supposed to insist on a method of detection being available, have recently laid down limits for 50 or more pesticides. (MAF 260/90, 13 February 1958)

To conclude, it was during the 1950s that MRLs were first seriously discussed as a regulatory tool. While the Scientific Sub-Committee generally appeared to favour their implementation this was often not borne out in practice; several reasons were cited as to why the calculation and imposition of limits would be both impractical and unnecessary. An issue that was repeatedly raised was the lack of data available and the inadequacy of testing facilities. There was therefore a concern among Committee members that limits would be devised on an administrative rather than scientific basis. Therefore, while other European countries and the U.S. calculated and set legally enforceable limits, England and the rest of the UK remained reliant on its voluntary scheme; a point that appears to have frustrated several MAFF officials and indicates that the position of MAFF towards industry was a source of tension within the organisation.

The influence of industry can be keenly seen as the Committees was acutely aware that the Notification Scheme was voluntary and as such there appeared to be a feeling among members that they should be as accommodating as possible with industry to ensure continued cooperation. Indeed, as a result of listening to industry requests and concerns surrounding trade secrecy, a scheme of secret notification was enacted, with the result that decisions could be made on the opinion of one elected reviewer.

4.34 3rd Working Party Report: Risks to Wildlife

The third Zuckerman Working Group Report "Risks to Wildlife" was released in 1955. As a result of this Report the remit of the Advisory Committee was widened to include the possible risks to wildlife from pesticide use.

Gilbert and Macrory (1989) detail how the interest regarding the effects of pesticides on wildlife grew during the late 1950s, largely as a result of the introduction of new pesticides such as seed dressings, Dieldrin and Aldrin. The authors (ibid) state that while farmers and wildlife organisations began to report damage to wildlife that they believed to be the result of pesticides, the extent and cause of damage was questioned by both MAFF and industry. The House of Commons Select Committee was charged with investigating the phenomena, however, the evidence presented in support of farmers and activists' claims was considered by MAFF and industry to be unreliable, being based on anecdotal observations rather than hard science. A situation mirrored in the more

recent 2005 Royal Commission of Environmental Pollution investigation into the effects of bystander exposure, which I discuss in Chapter Six.

4.4 1960s–1985: Recognising risk and emerging calls for statutory control

Following the Zuckerman Working Group Reports of the 1950s the issue of whether to introduce pesticide legislation was repeatedly discussed from the early 1960s up to the introduction of the Food and Environmental Protection Act (FEPA) in 1985. This section considers those discussions, outlining the reasons as to why a voluntary scheme was maintained.

In 1960 MAFF was asked to consider the problems that were likely to arise through continued use of the voluntary notification scheme. MAFF's report, as others before, stressed that "wherever possible voluntary action should be used rather than legislation". Indeed, it suggests that the introduction of a statutory scheme may lead to hostility and a desire to "get round" requirements by industry (MAF 260/90). However, on the issue of whether all products should be notified, rather than just those deemed suitably toxic, it praised industry, stating that in its opinion manufacturers tended to err on the side of caution, adding that widening the scheme would "create a lot of unnecessary work which would seriously curtail the time and energy – which can be devoted to really important matters" (MAF 260/90). Additionally, there were serious concerns expressed that official approval, including recommendations on

labelling, could expose the government to litigation if accidents occurred through the use of *'approved'* substances.

The issue of setting residue limits was once again raised, though doubts were expressed as to how well it could be enforced. Of particular note is a discussion on the need to take into consideration the use of multiple products on the same crop and the possibility of a cumulative effect for the consumer, suggesting that there were concerns over the effects of exposure to multiple pesticides as far back as the early 1960s. In particular, Professor Sir Charles Dodds, an eminent biochemist and Chairman of the Food Additives and Contaminants Sub-Committee, is described in an internal MAFF memo as worrying about the large number of residues that were being carried over into foods and the fact that "they knew little or nothing about the interaction of one on another" (MAF 260/216, 1961).

4.41 The classification of pesticide residues

As the use of pesticides in agriculture leads to the presence of residues in food, discussion on the setting of residue limits was undertaken by both the Advisory Committee on Poisonous Substances and the Food Additive and Contaminants Sub-Committee (FACS). However, the FACS was keen to highlight that operational differences in the two committees raised certain difficulties; most notably that the FACS' function was to make proposals for regulation, whereas the Advisory Committee's was to manage a voluntary scheme. It was therefore felt by the FACS that enforcing regulations governing the incorporation of intentionally added

additives in food was easier than controlling the residues of chemicals applied to growing crops.

The FACS, in keeping with its principle that chemical additives in food should be kept to a minimum, advocated a general principle of permitting only one of several effective substances to be used for a particular purpose in food. It stated that this decision should be based on factors such as relative toxicity, amount required and potential for interaction. However, while this is a key principle for additives it argues in support of the Scientific Sub-Committee's views on substitution; that these distinctions cannot be adequately applied to pesticides due to a wide variation in application conditions. In particular, it was felt that there were unpredictable factors, such as differences in growing environments and changing weather, which could alter the level of pesticide residues found in crops. It was believed that this variation would increase the difficulty of setting and enforcing MRLs. A key concern in this respect was apportioning blame if excessive residues were detected, i.e., was it the responsibility of the grower, the distributor or the manufacturer? It was therefore felt that the setting of enforceable limits and applying the same regulatory principles as used for additives to pesticides would remain difficult under a voluntary scheme (MAF 260/216, 1961. PS 351).

Despite these concerns there was no discussion within the document recommending a move to a statutory regime. Instead, the Scientific Sub-Committee made the suggestion that the only practical way of checking that the voluntary scheme was working was to regularly sample food crops to measure the level of residues present (MAF 260/216, 1961,

FSC/FAC/MIN/4). An internal MAFF memo indicates crops would be sampled at harvest to reduce the doubt of responsibility if excessive residue levels were discovered (MAF 260/216, 1961).

These discussions are significant in the history of pesticide regulation as this appears to be one of the earliest discussions surrounding the classification of pesticides for regulatory purposes. The discussions between FACS and the Advisory Committee suggest that it was here in the early 1960s that the decision was made to not classify pesticides as either an additive or a contaminant, but to treat them as a separate entity for which separate regulations would apply[21].

Additionally, it is noteworthy that the justification to treat pesticides as separate is grounded in ideas of intent and an acknowledgement of the complexity and variation found in farming conditions. Contingencies that in other pesticide risk discussions have been used by MAFF to justify inaction, as is shown in 4.42 where discrepancies between MAFF assumptions and the reality of farming practice is discussed (Health and Safety Executive, 1978; Irwin, 1995).

[21] This classification remains today. In the UK pesticides are not viewed as additives as they have no functional value in food at the time of consumption and many residues will have degraded to non-detectable levels by the time the food is consumed. They are also not treated as a contaminant as they are deliberately applied to protect crops. The exception is for water where they are treated as a contaminant.

4.42 The Pesticide Safety Precaution Scheme (PSPS)

In the early 1960s, the requirements of the notification scheme were revised under the Pesticides Safety Precaution Scheme (PSPS). The remit of the PSPS was to enable the government to provide advice on precautionary measures related to the use of new agricultural pesticides. The PSPS was a continuation of the previous voluntary agreement and required manufacturers of new chemicals to provide a data package outlining the safety of the product. This package was to include information regarding toxicity and persistence, however, data confirming efficacy[22] was not required (Russell, 2005). In several respects, the PSPS appears to have been a progressive move as it required data on the possible effects of pesticide use on product users, consumers of treated produce and the potential damage to wildlife and the wider environment. Indeed, following the introduction of the PSPS the key safety recommendations for each substance were now published on the product label. Labels included information on protective clothing and advice on the necessary levels of application to treat produce, which were designed to

[22] The gap in data regarding the efficacy of the crop protection products was met by the introduction of the voluntary Agricultural Chemicals Approval Scheme (ACAS), which required that any chemical submitted had already been accepted by the PSPS. Approval by ACAS was based on data submitted by the manufacturers in conjunction with tests carried out by the Advisory Services. Although voluntary, once a product had been approved by ACAS it was allowed to use a *'recommended'* emblem on the product indicating that the material had been tested and shown to work (Russell, 2006).

moderate the amount of residues found on crops. However, these were not legally enforceable and MAFF remained reliant on user compliance.

In 1964, the Advisory Committee on Poisonous Substances began a three year review of safety control arrangements concluding that the existing scheme worked well. In particular, it praised the co-operation between government and industry, stating that the voluntary arrangements allowed flexibility and low operating costs (Department of Education and Science, 1967, II (10)). Despite these benefits the Advisory Committee was concerned that the voluntary scheme did not offer enough protection on products that had not gone through the PSPS process. As a result, in 1967 the Advisory Committee recommended that a mandatory scheme be introduced, which would impose stricter conditions of use (Department of Education and Science, 1967, 168.(1)).

The Royal Commission on Environmental Pollution (RCEP, 1979) suggested that at first the Association of British Manufacturers of Agricultural Chemicals supported this recommendation. However, although legislation was drafted in 1968 it was never enacted, largely due to greater support for voluntary arrangements by Ministers in 1972. The issue of legislative control of pesticides was again raised in 1979 by the RCEP whose seventh report suggests that while industry were initially responsive to statutory control they were wary that legislation would be based on political rather than scientific considerations; which they argued would increase costs and registration times with little improvement in safety or efficiency (Royal Commission on Environmental Pollution, 1979). The Advisory Committee on Pesticides (ACP) was also not in favour. van

Zwanenberg (1996) proposes that its reasons were largely based on the fear that such legislation would place a strain on the already limited number of toxicological experts and would be timely and expensive, requiring the hiring of additional staff. The eventual impetus for change was not a desire to increase pesticide safety but a ruling in the 1980s by the European Commission stating that the UK was in breach of Community trading rules.

A key discussion during the 1964 review was on the setting of residue limits, with the Committee recommending that more food residue data be collected. However, it was clearly stated that "tentative residue limits" for active ingredients should only be established once sufficient data had been collected, and only once these limits have been in place for a *'reasonable'* length of time should they be replaced with statutory limits (Department of Education and Science, 1967, 168.(30-32)).

To check that users were applying the correct amount of pesticides, produce surveys were undertaken by the Working Party on Pesticide Residues to monitor the levels of residues in food, the results of which fed into total diet studies (RCEP, 1979). However, the first report of the Working Party in 1978 concluded that total diet studies were no longer necessary, a decision which was supported by the Scientific Sub-Committee on Pesticides (MAF 256/316, PS 3134). Despite these conclusions in 1979 the Steering Group on Food Surveillance stated that while total diet studies "could not be justified on a scientific basis...[they have] proved cost effective and beneficial from the political point of view" (MAF 256/316, 15 October 1979). In particular, it was felt that this

survey method was an excellent presentation tool which could be used to defend Britain's residue monitoring policy to European counterparts, and hence defend the voluntary nature of the PSPS and the use of non-statutory MRLs. The Steering Group highlighted that during 1967-1977 the surveys did not demonstrate any residues at levels that were of concern. However, the Group later acknowledged that the favoured method of analysis may have resulted in the dilution of residues, reducing them to a level below the limit of detection (MAF 256/316, 15 October 1979). This suggests that at this time the method of analysis was inadequate at determining whether levels had been breached and therefore whether the public were at risk.

The monitoring of residue levels in the UK was again discussed in the 7th RCEP Report (1979) where it was reiterated that the practices undertaken within the UK were out of line with other members of the European Community. In particular, it was noted that in contrast to the UK, other European countries both routinely sampled and tested individual food stuffs and removed from sale food items which were found to contain residues above agreed levels, singling out farmers who practised poor pesticide management. The RCEP argued that such schemes served to improve customer protection and encouraged a more conservative use of pesticides. However, minutes from the Steering Group meeting indicate that members felt the method to be less cost effective than total diet surveys, as it placed greater demands on laboratory facilities which, as previously discussed, were in short supply.

Watterson (1990), suggests that although many involved believed the PSPS scheme worked well, there were equally those that felt the PSPS was limited in its effectiveness and was unduly secretive. The PSPS, as in previous arrangements, ensured that all submitted data were handled confidentially, to ensure trade secrecy. However, the RCEP noted that confidentiality was often extended beyond the data submitted by industry to include any related information - such as that on the side effects linked to pesticide exposure - with the result that the public were effectively denied the ability to input or access information (RCEP, 1979). It is also noteworthy, that while industry actors were not present on the two main committees they were allowed on several expert panels. These panels advised the Scientific Sub-Committee on aspects such as labelling, industry was also encouraged to negotiate with the secretariat in respect to testing criteria and the type of data required for product notification (Gillespie *et al.*, 1979). This close working relationship was reflected upon by the RCEP (1979) who, like others such as Platt (1955), highlighted the resultant mutual advantages for both government and industry.

A key question of the RCEP's 7th report (1979) asked: *What is the underlying policy towards pesticide use?* It is clear from the report that the RCEP had serious misgivings surrounding the continued reliance on voluntary agreements. Indeed, the RCEP suggested that the best way to both reduce pesticide usage and ensure that all chemicals were adequately tested before use would be to enact a formal policy as per the practice in countries such as the Netherlands, Japan and parts of the USA. However, despite both an increase in use and reliance upon pesticides, it

stated that the need for such a policy appears not to have been considered in the UK:

> The MAFF view, and that of the agricultural and agrichemical industries, is that provided the chemicals are applied properly in accordance with the manufacturer's instructions their safety is ensured through the testing undertaken as a requirement of the PSPS; that the cost of pesticides discourages excessive use; and that the knowledge and experience of farmers, backed up by advice from manufacturers and from ADAS, ensures the necessary care in use and the selection of the most effective products. (Royal Commission on Environmental Pollution, 1979, 3.74)

The above statement offers an insight into how MAFF justified its continued advocacy of voluntary agreements over the establishment of statutory powers. It suggests MAFF made a number of assumptions in its continued support of the PSPS; most notably that all products would be submitted for review and that its testing criterion, which had been negotiated with industry, was adequate to ensure safety for both users and consumers. Additionally, it assumed that once cleared, all products will be correctly labelled and instructions adhered to. As in previous voluntary schemes, these assumptions placed the onus of responsibility for safe use on the user rather than the regulator.

Examination of official literature from the Health and Safety Executive (HSE) suggests that in many instances these expectations of good

practice did not occur. For example, the HSE stated in its publication *Agriculture 1976* (1978) that some manufacturers "were slow to bring their container labels up to date". Such labelling failures are believed likely to have contributed to the 46 reported pesticide related incidents in 1976 that included burns, dermatitis and neurological poisoning (Health and Safety Executive, 1978). This publication also details that despite inspectors providing demonstrations of 'safe' pesticide use at agricultural shows and during farm visits, they were often unsuccessful in changing farming practice. Likewise, in the publication *Agriculture 1977* (Health and Safety Executive, 1979) the HSE stated: "a lot of work still needs to be done to improve their [older farmers] knowledge and to change their attitudes". While these examples relate to occupational safety they illustrate how assumptions made at a Ministerial level did not always match the day-to-day reality. This suggestion has been made by others including Irwin (1995) who in researching the herbicide 2,4,5-T argued that the ACP's focus on the *"recommended way"* and *"recommended purposes"* was often at odds with reality. Such examples highlight that there was often a gap between advice and its implementation and suggest that voluntary agreements may have been partly responsible for inadequate product labelling and associated operational risks.

In summary, it can be argued that until the Food and Environment Protection Act (FEPA) 1985 there was little change in the way pesticides were regulated within England, though calls for statutory controls were emerging. The PSPS maintained the close working relationship between UK Government and the crop protection industry, encouraging mutual trust between the two. In this sense, industry was able to work closely

with government committees to ensure that products were accepted quickly and with minimal experimentation and administrative costs. However, actors such as the RCEP argued that the process was unduly secretive and was in effect closed to anyone outside of the inner circles of the advisory community. Thus, during this period pesticide policy was largely developed between government and its client groups, effectively leaving the public and non-experts outside of assessment and regulatory discussions.

Despite other countries adopting legally enforceable MRLs, the UK did not move towards the position of statutory limits. Instead, a series of residue surveys were undertaken as a mechanism to check good agricultural practice. There are several suggestions made in memos and literature taken from that period that indicate that there was a continued shortage of laboratory and methodological resources with which to analyse pesticide residues and that sampling methods may have resulted in lower residues being recorded than were actually present.

4.5 1985–1991: Food and Environmental Protection Act (FEPA) and the introduction of statutory limits

The effectiveness of existing residue controls were again examined in 1980 by the House of Lords Select Committee on the European Communities. The report indicates that there was unanimous support for the continuation of existing controls (including voluntary notification and non-enforceable MRLs) by those organisations who submitted evidence to

the Committee (MAFF, 1986). Despite continued advocacy for non-statutory limits, in 1985 the Food and Environment Protection Act (FEPA) was passed, which replaced both the PSPS and ACAS. Part III of the Act gave MAFF Ministers broad powers to:

> protect the health of human beings, creatures and plants; safeguard the environment; secure safe, efficient and humane methods of controlling pests; and make information about pesticides available to the public. (HMSO, 1985, Part III S.16)

In particular, *S.16 (12)* of FEPA states that any contravention of regulations, conditions of approvals, requirements or knowingly supplying false information and failing to disclose key data was now considered an offence (HMSO, 1985). Specifically, S.16 (2. k & l) states that Ministers may now through regulations:

> specify how much pesticide or pesticide residue may be left in any crop, food or feeding stuff; and direct that, if there is more pesticide or pesticide residue in any crop, food or feeding stuff than the portion specified by virtue of (k) above, either of the Ministers shall have power-
>
> (i) to seize or dispose of the crop, food, feeding stuff in question or to require that some other person shall dispose of it;
>
> (ii) to direct some other person to take such remedial action as appears to the Minister to be necessary as a result of the contravention.

The above illustrates that the enacting of FEPA signified a significant change in the way that pesticide residues in food were regulated within England with a move away from voluntary agreements. The decision to develop legally enforceable residue limits can also be seen as the start of the UK's integration within the European Community with respect to harmonising pesticide policy.

FEPA was updated the following year under the 1986 Control of Pesticides Regulations (COPR) (HMSO, 1986). COPR further enhanced pesticide safety by requiring commercial users to be sufficiently trained to handle pesticides so to safeguard the health of humans, wildlife and the environment. Importantly, COPR defined the pesticides that were subject to control and set out an approval scheme that was to be satisfied before any pesticide could be stored, supplied, used or advertised (HMSO, 1986).

The implementation of FEPA and COPR enabled a greater legal control by the UK Government over the manufacture, distribution and use of pesticides. However, it has been argued by some social researchers that because the requirements were set out in regulations and codes of practice, as opposed to primary legislation, there was a high degree of flexibility in the regulatory framework that allowed for changes and adaptations (Gilbert and Macrory, 1989).

4.51 Maximum Residue Levels: Legal enforcement

The Pesticide Residues Committee defines Maximum Residue Levels (MRLs) as:

> The maximum concentration of pesticide residue (expressed as milligrams of residue per kilogram of food/animal feeding stuff) likely to occur in or on food and feeding stuffs after the use of pesticides according to Good Agricultural Practice (GAP)[23], i.e., when the pesticide has been applied in line with the product label recommendations and in keeping with local environmental and other conditions). (Pesticide Residues Committee, 2008)

It is important to note that MRLs are used only as a check in the monitoring of pesticide use (Defra, 2007a) and are not a health-based exposure limit. They are therefore not linked to pesticide safety limits such as the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD)[24]. However, the Pesticide Safety Directorate state that pesticide use would not be allowed if the MRL led to exposure greater than either health-based limit (Pesticide Safety Directorate, 2008).

[23] Good Agricultural Practice (GAP) is the nationally authorised safe use of pesticides under actual conditions necessary for effective and reliable pest control. Good practice should ensure that crops are left with the smallest residue achievable (MAFF and HSE, 1990).

[24] See Chapter Five for definitions.

I have highlighted that prior to 1985, the UK, unlike its European counterparts, resisted the introduction of legally enforceable MRLs[25] in favour of voluntary agreements. I discussed that this reluctance towards statutory control was originally attributed to the argument made by the Advisory Committee on Poisonous Substances used in Agriculture and Food Storage and its Scientific Sub-Committee that there was insufficient scientific data to establish MRLs. However, by 1986 MAFF documents suggest that the UK's reluctance to impose statutory limits was beginning to undermine its position with Europe; other member states questioned whether the UK's reliance on voluntary controls gave farmers "the advantage of less stringent standards" (MAFF, 1986, p.5). The desire for credibility within Europe and the belief that adoption of statutory limits would increase trade can therefore be seen as an impetus for change within England and the UK.

The new law was also believed to be more protective of human health. Gilbert (1987) notes that although the Food and Drugs Act (1955) (changing to the Food Act 1984) provided statutory protection against the sale of food that was dangerous to health, it was not routinely applied in respect to pesticide residues. Indeed, a FEPA consultation document from MAFF states that residue levels would have to be "extraordinarily high in order to render the food directly injurious to health and thereby secure a

[25] Although the changes were introduced in the 1985 FEPA, it was the 1988 Pesticides (Maximum Residue Levels in Food) Regulations that bought these changes into effect. These regulations stated that MRLs would be determined as far as possible in accordance to guidance provided by the Codex Commission.

conviction under section 1 of the Food Act" (MAFF, 1986). In defending England's previous reliance on the Food and Drugs Act the same document (ibid, p.5) states that this Act was "introduced originally to control the gross alteration of food before it was realized that very low quantities of contaminants might also present a risk to the population if ingested over long periods". Such a statement suggests MAFF has a poor long-term institutional memory; in addition to highlighting the dangers faced by operators through repeated low-level exposure to OP pesticides (1951), the second Zuckerman Report (1953) on consumer risk repeatedly highlighted that chronic exposure to low-levels, through the consumption of residues in food, posed a potential health risk. Both of these reports were published before the introduction of the 1955 Food and Drugs Act, thus suggesting that the issue of chronic low-level exposure has been repeatedly sidelined within the assessment and regulatory community.

From the 1980s onwards several European directives have related to MRLs for pesticides in foodstuffs, including Article 100a of the 1986 Single European Act and the 1990 Directive on Residues in Fruit and Vegetables. The aim of European MRL guidelines was to enable trade across the European Community. Although the European guidelines referred to the work of the World Health Organisation's Codex Alimentarius Commission[26], the European MRLs were often more conservative than the

[26] The Commission was established in 1963 to provide food standards and guidelines with the aim of unifying and integrating individual country levels to promote international trading (FAO and WHO, 2006). Although there was no enforceable legal framework for the implementation of

comparative Codex values (Hough, 1998); either reflecting Good Agricultural Practice (GAP) that applied to Europe only, or representing a politically negotiated compromise between different national limits (MAFF, 1986). European MRL values were typically decided upon by an expert panel that assessed relevant scientific literature and food survey data, with experts drawn from across member states. The discursive process thus suggests that MRL limits are not based wholly on scientific data but are negotiated and shaped by social and political values.

The European Commission (EC) is currently in the process of setting MRLs for over 600 foodstuffs and has set levels for approximately 200 (Pesticide Safety Directorate, 2006b). It was in 1990, following the Directive on Fruit and Vegetables, that the UK began to routinely adopt EC MRLs. Today, where they are available, EC MRLs are the default values if there are no UK temporary MRLs or imported tolerances, these take precedence over other UK national or Codex values (Pesticide Safety Directorate, 2006b). However, it should be noted that the EC Directives containing the MRLs are only enforceable in the UK if they have been transposed into national legislation (Defra, 2007a).

To summarise, the passing of FEPA and COPR and the adoption and enforcement of MRLs can be seen as a move away from the voluntary schemes that characterised pesticide regulation for much of the 20th Century and have helped align the UK with other European Community

---

Codex MRLs until 1995 (FAO, 1995), their use was encouraged by the United Nations Resolution 39/248 (United Nations, 1985).

members. However, there were still concerns present regarding the scientific basis of these limits.

4.6 1991: European harmonisation & the Plant Protection Products Directive

The European Union is in the process of harmonising pesticide regulations under the Plant Protection Products Directive 1991. The approval of pesticides in the UK is therefore in transition from a national system based on FEPA and the 1986 regulations (as amended) to a European system set out in Directive 91/414/EEC (EEC, 1991). Presently, there are two parallel approval systems in EU member states where the scientific evaluation of pesticides is carried out at either a national or European level. Under both systems there are four approval levels; Experimental Approval, Provisional Approval, Full Approval and Emergency Approval.

It is hoped that harmonisation will enable a greater degree of trade and ensure that all member countries are compliant with centrally set standards such as MRLs; thereby providing a safety baseline across Europe. An additional benefit of harmonisation will be the creation of a central database (Annexes), which should in theory help to decrease duplication of research (in turn reducing the number of animals used in research) and shorten registration times.

To register a new product under the Directive, companies must choose a member state to who they will submit their scientific data dossier. The member state will evaluate the data to ensure that they comply with the

Directive requirements concerning safety to humans and the environment. If acceptable, the member state will then submit a report to the Commission where it will be passed to the Standing Committee on the Food Chain and Animal Health (SCFA) to be considered by other member states. If deemed acceptable, it will be listed in Annex 1 (Defra and Health and Safety Executive, 2005).

In the UK, the Directive was implemented in 1993 changing to the Plant Protection Products Regulation (PPPR) in 1995, now the PPPR 2003. In the UK, it is the Pesticide Safety Directorate[27] (PSD), an agency of the Health and Safety Executive, who is responsible for pesticide registration (Health and Safety Executive, 2007). In addition to registration, the PSD has the responsibility of providing advice to Ministers regarding the development and enforcement of pesticide policy and legislation (Defra and Health and Safety Executive, 2005). Although the PSD is responsible for the registration of pesticides, it is the Advisory Committee on Pesticides (ACP) which assesses and evaluates the data packages submitted by manufacturers. Indeed, it is required by law that the ACP be involved in every decision regarding the granting, amending or revoking of approval. However, although the ACP provides advice, the final approval decision is taken by Ministers (ibid).

[27] Until April 1st 2008 the PSD was an Executive Agency of Defra. It was transferred to the Health and Safety Executive (as an internal agency) following Defra's review of its regulatory agencies and the recommendations made in the 2005 Hampton Review of Regulators. It should be noted however that the strategic policy responsibility for pesticides will remain with Defra Ministers (Health and Safety Executive, 2008).

In 2008 there were 18 members of the ACP including the Chairman and Deputy Chairman; with the exception of the two lay members (a relatively recent phenomenon) all members can be viewed as having scientific expertise, most notably in human or environmental toxicology – this is further discussed in Chapter Seven. While it is increasingly difficult to find advisory members who have no link to industry, the Code of Practice for the ACP is clear in stating that all interests should be publicly recorded and those employed in the pesticide industry or holding a directorship are not eligible to join (Defra, 2001, 6.1), members therefore tend to be leading academics who sit on multiple committees relating to pesticides. Members meet several times a year and although there have been calls by campaign groups to introduce open meetings they remain closed to the public on the grounds of commercial confidentiality.

At a European level there are several different working groups and committees who regulate and provide advice regarding pesticides. In addition to the Council and European Parliament, pesticides fall under the remit of the European Food Safety Authority (EFSA), several regulatory and scientific committees and various working groups including the Working Group on Pesticide Legislation (Defra and Health and Safety Executive, 2005). This division of responsibility is mirrored in the UK where there are now several bodies involved in the regulation of pesticides, leading some in the field of pesticide risk assessment to suggest that European harmonisation has increased bureaucracy (Marrs and Ballantyne, 2004). For example, in addition to the ACP the following bodies are also involved in UK pesticide regulation: the Pesticide Safety Directorate (PSD); the Pesticide Residues Committee (PRC); the Biocides

and Pesticides Unit; The Environmental Panel; The Medical and Toxicological Panel; The Inter-Departmental Secretariat (IDS); The Biocides Consultative Committee and the Pesticides Forum (Defra and Health and Safety Executive, 2005). These individual bodies are not centrally governed but fall under the remit of a variety of UK agencies including: Defra; the Environment Agency, the Health and Safety Executive; the Food Standards Agency; the Department of Health and various regional departments. This diffusion of regulatory power has been criticised by several NGO groups and pesticide activists, including the Pesticide Action Network[28], on the grounds that issues relating to pesticide approval, use and effect are artificially separated and therefore harder to manage in a holistic manner.

In addition to those listed above, advice to consumers regarding the consumption of pesticide residues in food is now also provided by the Food Standards Agency (FSA). While the FSA is not involved in the assessment and registration of pesticides it has commissioned reviews through the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)[29] and undertaken research on the

[28] Taken from interview data.

[29] The COT is a scientific committee that was established by government in 1978 to provide advice to MAFF and various other government departments on issues relating to the toxicity of chemicals. In discussing chemical risks in food COT states that it: “aims to form an objective view on the available evidence in a way that recognises both uncertainties and assumptions and considers the possible variation in interpretation of scientists working from different standpoints” (Committee on Toxicity, 2008).

risks faced by consumers from the consumption of pesticide residues in food. In response to a growing concern surrounding the effects and potential risks surrounding human exposure to pesticide mixtures it produced the following report: Risk Assessment of Mixtures of Pesticides and Similar Substances (Committee on Toxicity, 2002b). The publication of this report has led to a further review by COT on the Variability and Uncertainty in Toxicology of Chemicals in Food, Consumer Products and the Environment (Committee on Toxicity, 2007) and a research programme entitled: Mixtures: Toxicology and Exposure (T10), which is investigating the tools required to study the interactions of pesticide mixtures during the risk assessment process (Food Standards Agency, 2008).

To summarise, the introduction of the Plant Protection Products Directive 1991 has seen a move towards European harmonisation. While harmonisation has recognised benefits, most notably in the creation of a safety baseline across member states, there are also drawbacks with the process of assessment and registration perceived to be more bureaucratic than in previous decades; there are now several agencies within England and the UK that work in the area of pesticide regulation and risk communication, each of whom have a different remit and agenda. These differences have resulted in tensions between advisory bodies, a theme that is discussed in detail within Chapter Six. As in previous decades the risk assessment of pesticides for regulatory purposes is still undertaken in closed meetings by those perceived to have toxicological and scientific expertise. Whilst, in previous decades members of committees, such as the ACP, were predominantly government employees, members are now

likely to be leading academics, many of whom are serial professional committee members. However, there has been a recent move among advisory committees, in an attempt to both increase procedural transparency and reduce the public perception of industry bias, to include lay members within the committee.

4.7 Summary

In this chapter I have illustrated how decisions made during the 1950s and 1960s have directly shaped the role and remit of current English pesticide advisory bodies. Specifically, I illustrated that decisions taken in the 1960s mean that pesticide residues are not classified as either a food contaminant or additive; the result of which is that they are subject to different assessment and regulatory processes.

I detailed how statutory regulation has evolved through a succession of voluntary agreements that were underpinned by mutual trust between government and industry. I highlighted that despite other countries' willingness to implement statutory controls and the legally enforceable Maximum Residue Levels (MRLs) this move, while debated internally within MAFF, was ultimately resisted by the UK Government which favoured placing the burden of responsibility on industry and pesticide users.

I suggested that industry welcomed this resistance, as continuation of voluntary practices allowed them to work closely with government departments, providing them opportunity to help shape assessment

requirements and ensure a quick and efficient approval process. A key argument made by government in favour of maintaining the voluntary process was that there was a shortage of both resources and skills with which to undertake statutory assessment and the setting and checking of MRLs. Indeed, I illustrated using the example of Schradan that there was a perception among government departments and advisory groups that it could take years to analyse an individual pesticide substance. In discussing this, I showed how there were concerns that the setting of statutory residue limits would mean proposing limits that were not scientifically established but adopted purely for administrative purposes; a position that was largely seen by those involved as unsatisfactory.

Importantly, using archival evidence I suggested that in several instances the expectations of good practice by industry and pesticide users did not occur in reality. Notably, memos from the 1970s indicate that where residues were being monitored the methods used to analyse residue levels were questionable and may have led to artificially low-levels being recorded. As such the true extent of risk facing the public is likely to have been unknown. Additionally, I highlighted that advisory bodies were reluctant to consider alternate types of evidence that fell outside that provided by industry or that collected by government departments. Where evidence was assessed it was felt by industry that it should only be assessed by those with expertise, preferably toxicological, and that the process should remain as confidential as possible. These requirements can be seen as having shaped the make up of pesticide committees working today, such as the Advisory Committee on Pesticides (ACP) that

still holds its meetings in private and has only relatively recently introduced two lay-members.

In particular, I have demonstrated that from the 1950s onwards there were serious concerns raised relating to chronic exposure to low-levels and exposure to mixtures of pesticides. I have illustrated using archival evidence that despite these concerns being referenced throughout this period they have been persistently bracketed within the assessment and regulatory process, with the effect that discussion of these concerns has effectively been removed from the remit of pesticide advisory bodies such as the ACP. Indeed, although more recently there has been a move to investigate these concerns by the Food Standards Agency. The very fact that these concerns are still present sixty years from when they were first raised suggests that despite significant technical and scientific developments in the area of risk assessment, the fundamental questions we are asking about the risks of exposure to pesticides have not significantly altered since the first consumer review by Zuckerman in 1953.

Chapter 5: Management of Uncertainty in the Risk Assessment of Pesticide Residues

5.1 Introduction

In the previous chapter I showed that the fundamental questions that are being asked today about the risks of exposure to pesticide mixtures through food were already being raised throughout the early history of pesticide regulation. In this chapter I step behind the regulations to explore the toxicological science[30] on which pesticide reference doses[31], and hence risk advice, is derived. In doing so I seek to answer the following research question*: How are the potential risks of pesticide residues in food assessed in the current advisory system for regulation and why has this system been challenged?*

In this chapter I will illustrate that the historical regulatory separation of pesticides from other environmental and food contaminants, as discussed in Chapter Four, has today resulted in pesticides being treated as an anomaly, which does not conform to the standard environmental risk assessment framework used within Defra. Instead, the regulatory requirements and assessment guidelines are now largely determined at a

[30] The thesis is primarily concerned with human exposure I will therefore discuss those assessments relevant to human toxicity.

[31] This thesis is only concerned with pesticides that are classed as chemical substances as found in Part A of Annex II of the Directive 91/414/EEC (Office for Official Publications of the European Communities, 1991).

European level and managed within the UK by the Pesticide Safety Directorate (PSD) and the Advisory Committee on Pesticides (ACP), which assesses industry produced data dossiers for the purpose of registration.

I will highlight that risk assessment can be broken down into four interlinking stages that combine science and expert judgement. In this chapter I focus on the second stage of risk assessment, hazard characterisation. I discuss - using a combination of scientific literature and policy documents, and interview data taken from scientists and members of government advisory committees - that in the assessment of pesticides there has historically been a reliance on *in vivo* methodology. The benefits and drawbacks of this practice, as conceptualised by those working in the field, are discussed and it is suggested through the evidence presented that although decisions surrounding testing requirements are purportedly objective through increased levels of standardisation, the decisions as to how tests are designed and selected for use in determining human reference doses are shaped by historical, social and pragmatic considerations.

Lastly, I explore a key area of challenge and uncertainty in pesticide risk assessment which concerns the question of how to study and assess chemical mixtures. I suggest that the study of chemical mixtures has historically received limited attention within the regulatory and risk advisory community for two reasons: 1) a perceived difficulty by regulators and scientists in conducting the science, and 2) a belief that it is a non-problem when individual components are present at an acceptable level. Where mixtures have been addressed researchers have

typically favoured undertaking simple studies using binary mixtures at high doses. In doing so the complexity found in real life exposure is likely to be reduced, suggesting that the true scale of uncertainty will remain indeterminable.

5.2 Risk assessment guidance & legislation

An important feature of the information pertaining to pesticides is that the evidence considered as acceptable for use in assessment is largely determined and standardised by regulatory requirements and framed by the criteria imposed by the UK Government and European Union. Such regulatory frameworks are frequently viewed as beneficial by those within the risk assessment community as they stipulate minimum data requirements, which aim to provide risk assessors with the necessary information (as believed by the regulatory authorities), to undertake informed evidenced-based decisions. Mandating evidence requirements also means that in theory each substance is assessed on equal grounds and that risk can be easily compared. Although this has obvious merits, it creates problems for the acceptability of new methods that purport to assess the effects of mixtures but that current regulatory guidelines do not recognise.

5.21 European harmonisation

In Chapter Four I outlined that while the Pesticide Safety Directorate (PSD) and Advisory Committee on Pesticides (ACP) are responsible for assessing pesticide risk assessment data in the UK, since 1991 the

information required is now largely determined at a European level through Directive 91/414/EEC (Office for Official Publications of the European Communities, 1991)[32].

For a pesticide to be approved, manufacturers must submit a technical dossier to the national assessment body of the country where they wish to market their product. The information required is detailed in the Directive 91/414/EEC under Annex II and must contain "information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment" (Office for Official Publications of the European Communities, 1991, 1.1)

For active substances in Annex II Part A, the submitted dossier comprises eleven categories of information, which includes toxicological and metabolism studies, and information pertaining to residues in or on treated products, food and feed (ibid). Notably, unlike other areas of environmental risk in the UK, the PSD and the ACP do not follow the formal risk assessment document Greenleaves 2[33] when assessing the

[32] The test requirements for active pesticide substances are set out in Annex II with the equivalent for formulated products set out in Annex III.

[33] Greenleaves 2 refers to the "Guidelines for Environmental Risk Assessment and Management" that was jointly developed by the Department of the Environment, Transport and Regions, The Environment Agency and the Institute for Environment and Health. Defra states that the guidelines "emphasises the establishment of risk assessment, risk management and risk communication as essential elements of structured decision-making processes across Government, and provides an over-

risk from pesticides (Defra *et al.*, 2000). Instead, they follow the "Uniform Principles" as detailed in Annex VI of Directive 91/414/EEC (Office for Official Publications of the European Communities, 1991), which is supplemented with guidance documents and procedures outlined in the World Health Organisation's (WHO) International Programme on Chemical Safety (IPCS) Environmental Health Criteria 104 and 210 (IPCS, 1990, 1999).

The current UK legislative framework regarding pesticides has been designed with the following four aims, which must be met if a pesticide is to be approved for sale and use (Defra and Health and Safety Executive, 2005, p.8):

- Pesticides should only be approved for use if they are effective;
- No-one should develop any serious illness through the use of pesticides;
- No-one should be harmed or made ill by the presence of pesticide residues in food or drink; and
- When pesticides are use in accordance to the conditions of their approval, any adverse effect on wildlife or the environment are sufficiently small to be deemed acceptable.

---

arching framework for the development of functional risk assessment guidance" (Defra *et al.*, 2000).

In the following part of this chapter, I will largely focus on category five of the required information in Directive 91/414/EEC, which relates to toxicological and metabolism studies. These studies are highly important as they are used to determine both the No Observed Adverse Effect Level (NOAEL) and the Lowest Observed Adverse Effect Level (LOAEL), which are utilised in the setting of human reference doses. There are currently three reference doses in respect to pesticides that are used within the UK and Europe; the Acceptable Daily Intake (ADI), the Acute Reference Dose (ARfD) and the Acceptable operator exposure level (AOEL)[34]. The ACP defines the ADI and the ARfD as follows (Defra and Health and Safety Executive, 2005, p.10):

> **Acceptable Daily Intake (ADI)**
>
> This is the amount of a chemical which can be consumed every day for a lifetime in the practical certainty, on the basis of all known facts, that no harm will result. It is expressed in milligrams of the chemical per kilogram bodyweight of the consumer. The starting point for the derivation of the ADI is usually the lowest "no adverse effect level" (NOAEL) that has been observed in animal studies of toxicity. This is then divided by an uncertainty factor (most often 100[35]) to allow for the possibility of that animals may be less sensitive than humans and also to account for possible variation in sensitivity

[34] The AOEL is not relevant to this thesis and so will not be discussed.

[35] The applied uncertainty factor is usually a combination of a factor of 10 to account for the inter-species differences and a factor of 10 to account for intra-species differences, though this may vary by substance.

between individuals. The studies from which NOAELs and hence ADIs are derived take into account any impurities in the pesticide active substance as manufactured, and also any toxic breakdown products of the pesticide.

Acute Reference Dose (ARfD)

The definition of the ARfD is similar to that of the ADI, but it relates to the amount of a chemical that can be taken in at one meal or on one day. It is normally derived by applying an appropriate uncertainty factor to the lowest NOAEL in studies that assess acute toxicity or developmental toxicity.

In this section I have discussed the regulatory framework that surrounds the assessment of pesticides and how this is increasingly determined at a European level. In the following section I move on to discuss the process of risk assessment.

5.22 Risk assessment: A four stage process

Risk[36] from exposure to chemicals is typically characterised through an assessment process that utilises both technical evidence and expert judgement (Benford, 2008). The conventional risk assessment paradigm, as used by Defra, consists of four parts: hazard identification, hazard

[36] Defra (2002) defines a hazard as: "any situation that in particular circumstances could lead to harm", and risk as: "a combination of the probability of the occurrence of a defined hazard and magnitude of the consequences of the occurrence".

characterisation, exposure assessment and risk characterisation (Defra, 2008). While the first three stages are purportedly grounded in scientific practice, the fourth stage, risk characterisation, can be better thought of as a hybrid of science, expert judgement and policy.

At the stage of hazard identification, the risk that a substance may pose is unknown; this stage is used to identify the inherent capacity of a chemical to cause adverse effects, although it is important to note that hazard does not always equate to a risk. Once these have been identified hazard characterisation will occur. During this second stage there will be a semi-quantitative evaluation of the chemical under study, which includes investigating factors such as dose response and toxic potency. The toxicity of a chemical is typically determined using a combination of three methods[37]: epidemiology, *in vivo* and *in vitro* methods. The resulting effect (or lack of effect) associated with exposure to a particular dose can be measured and used to plot a dose response curve. These curves are then used in the determination of the Lowest Observed Adverse Effect Level (LOAEL), the No Observed Adverse Effect Level (NOAEL)[38] and the No Effect Level (NEL).

[37] Recent methodological developments have seen a rise in computational methods based on toxico-kinetics to determine toxicity. However, these computational methods are yet to be widely accepted or officially validated for the purpose of regulatory decision-making and are not currently available for toxicity endpoints.

[38] This process refers to the testing of chemicals that are not carcinogenic and specifically non-genotoxic. Chemicals are typically assessed differently depending on their capacity to induce cancer, with non-carcinogenic chemicals typically working within a scientific model that is

The third stage of the risk assessment process involves assessing exposure. This is used to qualify the level of chemicals to which humans and the environment are exposed with regards to the magnitude, duration and frequency (Risk Assessment and Toxicology Steering Committee, 1999). Assessment of exposure is an important part of the risk assessment process; it is only through exposure that a chemical is upgraded from being defined as a hazard into a risk. There are three standard approaches used within exposure assessment: *direct methods* that measure exposure at the point of contact as it occurs; *indirect methods* that extrapolate estimates from existing data; *biological monitoring* (Fryer *et al.*, 2004).

The final stage is risk characterisation. Defra's (2002) definition of risk is the standard definition used in quantitative risk assessment, i.e., a combination of the probability of a defined hazard and the magnitude of occurrence. It is therefore an estimate of both the probability that an adverse effect will occur and of its severity, and duration in a given population under defined exposure conditions. To compensate for human genetic variability and for the differences between the animals used in toxicological studies and humans, an uncertainty/safety factor is used along side the NOAEL and LOAEL to calculate human reference doses. These doses are then used for regulatory purposes to protect human health and the environment. In the case of pesticides these are the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD). Risk characterisation is therefore based on both the information obtained in

---

grounded in the concept of threshold doses, where exposure to levels of chemicals below the threshold is seen as acceptable.

the first three stages of risk assessment and the context in which the assessment is conducted. It is therefore important when characterising risk to consider all available information from the first three stages and to check that all possible hazards and routes of exposure have been considered.

5.3 Regulatory pesticide toxicology

5.31 The dominance of in vivo methods

The toxicological assessment of pesticides relies heavily on the use of *in vivo* methods that use animals as a model for humans. Indeed, unlike pharmaceuticals, *in vivo* tests of pesticides are typically only carried out in animals[39]. A key benefit of using animals, as conceptualised by those working in toxicology and risk assessment, is that it not only allows scientists to accurately control the chemical dose administered but also the environment in which it is given. This practice therefore increases the likelihood of demonstrating a causal link between dose and effect; something which is recognised in scientific and regulatory literature as often impossible to do with human epidemiological information where there may be other confounding factors (Office for Official Publications of the European Communities, 1991; Defra and Health and Safety Executive, 2005). The difficulties of using epidemiological data were

[39] Intentional human dosing is not a recognised method of pesticide testing by the European Chemical Bureau and is therefore not required as part of the dossier provided by pesticide manufacturers (European Chemicals Bureau, 2006). However, when available it may be considered, provided that tests meet strict ethical guidelines.

recently discussed by the Head of the Food Standards Agency's (FSA) Chemical Risk Assessment Unit, who wrote that: "even when causality can be assumed, information on the degree and duration of exposure resulting in the reported effect is generally lacking or highly uncertain" (Benford, 2008).

In fact, epidemiological evidence is not always required in the assessment of new pesticides for the purpose of registration at either the UK or European level; it is unlikely that there will be enough associated population exposure data available at the time of assessment[40] (Office for Official Publications of the European Communities, 1991; Defra and Health and Safety Executive, 2005). Indeed, the use of epidemiological material in the risk assessment of pesticides was seen as problematic by the majority of the Advisory Committee of Pesticides (ACP) members that I interviewed:

> "the trouble with epidemiology studies in general is that they are very insensitive, you know you need enormous populations, the disease or the toxicity you are studying needs to be a rare occurrence and not a background in the population, you rarely have any idea about what dose levels people were exposed to, so there are so many variables that it is quite difficult to really say whether what you are measuring is true or not" (L) ACP Member

[40] Epidemiological data is part of the reassessment of older pesticides that have been in use over a number of years.

Epidemiology and exposure assessment are complex due to both the variety of chemicals that may be present, the possibility of multiple exposure routes and other confounding factors. This complexity is widely recognised amongst risk assessors such as the UK Risk Assessment and Toxicology Steering Committee (1999 b, p.9), who write that the process of assessing risk associated with human exposure relies on a "number of assumptions, estimates and rationalisations". For example, exposure modelling can rarely replicate the complexity of real exposure scenarios; as such they will only ever provide approximations of reality (van Veen *et al.*, 2001); suggesting that the very methods used within risk assessment, as a means of quantifying risk, can themselves become a source of uncertainty.

Likewise, although there are areas such as genotoxicity which are considered to be well established, there are many recognised difficulties that can affect the success and perceived reliability of *in vitro* methods, such as differences in tissue reaction and underestimation of toxicity when compared with *in vivo* studies (Timbrell, 2002). In regulatory pesticide assessment, *in vitro* tests are generally used as part of a tiered assessment process, where the results are used to determine what test procedure should follow – the proceeding tests will usually involve an *in vivo* methodology (Office for Official Publications of the European Communities, 1991; Whitford, 2002). This methodological hierarchy was discussed by interviewees such as (P), an academic toxicologist, who spoke of a novel *in vitro* study they had been researching, which they considered as robust but that would not be accepted by regulatory authorities due to a lack of confirmatory *in vivo* evidence.

In addition to the perceived advantages in terms of allowing experimental control, the use of smaller animals with short life spans and high fecundity allows for the monitoring of effects over both the lifespan of the animal and the lifespan of its offspring. Animals are therefore often seen within toxicology as a practical alternative to human testing as they can easily be housed and regularly examined and be commercially bred for different purposes; inbred strains are often perceived within toxicology as being able to provide more consistent results and animals can be specifically bred to be susceptible to certain diseases. Moreover, the fact that they have been used for several decades in regulatory risk assessment has acted to perpetuate their use; the information from past tests has created a database against which assessment authorities judge the toxicity of new pesticides (Whitford, 2002, p.25). Thus suggesting that regulatory authorities deem it necessary to continue to adopt such tests in order to establish and compare the toxicity of pesticides against each other and maintain a thorough database.

5.32 Challenges of animal use

Despite the preferential use of *in vivo* methodology, concern remains over the appropriateness of using animals as a surrogate model for humans. This reflects not only the ethics of animal use but also the scientific validity of extrapolating effects demonstrated in animals to humans.

Regulatory pesticide tests use a range of animals that typically include rats, mice, rabbits, guinea pigs and dogs. Depending on the type of investigation, tests may be required to be performed on more than one

species; usually rats plus an additional species (Committee on Toxicity, 2007). Although primate testing is undertaken and is accepted in regulatory risk assessment, it is not compulsory and several interviewees, including members of the ACP, commented that they would prefer primates not to be used as they saw no added benefit in their use.

In order to standardise tests at an international level, organisations such as the World Health Organisation (WHO) and the Organisation for Economic Co-operation and Development (OECD, 1982) have produced guidelines such as Good Laboratory Practice[41] (GLP), which since 1986 have to be adhered to within UK regulatory requirements for pesticides. These guidelines standardise testing techniques, including species choice, experimental design, and interpretation of test results. Like European harmonisation, adherence to these guidelines should in theory produce studies that are acceptable for use by multiple international agencies. It was therefore hoped by regulators that the introduction of international guidelines would reduce both the financial costs and the number of

[41] GLP and Compliance Monitoring were revised by the OECD in 1998 and adopted by the EU as Directives 99/11/EEC and 99/12/EEC. In 1999 the UK updated its regulations through SI 1999/3106 and later through SI 2004/994. The Medicines and Healthcare products Regulatory Agency (MHRA) define GLP as:

"GLP embodies a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived...GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments" (Medicines and Healthcare products Regulatory Agency, 2007).

animals used in toxicity testing e.g. through the setting of animal number guidelines and a reduced need for replication of experiments to meet the requirements of different member states[42] (World Health Organisation *et al.*, 2003).

In a recent report providing guidance on the setting of acute reference doses (ARfDs) for pesticides the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) stated that:

> The NOAEL from the most sensitive species should be used unless there is evidence to demonstrate it is not appropriate for a human risk assessment. (Solecki *et al.*, 2005 p.1574)

However, as was highlighted by (P), an academic mixtures toxicologist, this approach can only be thought of as flawed; to definitively know this information one would have to test every animal species, which (P) stated is clearly impossible. Additionally, the testing of the most sensitive species may not be realistic. For example, the cost of obtaining and housing the animal may be prohibitive, the animal may not cope in laboratory conditions or it may be banned or discouraged from use on ethical grounds.

It is therefore common that animals are selected for test purposes on practical grounds such as their availability and ability to survive

[42] In relation to pesticides this goal was formally recognised in the 4th stage review of the EU Directive 91/414/EEC on Plant Protection Products in Article 5:2 and in Article 8 (2): 11 (European Commission, 2004b).

laboratory conditions (Santillo *et al.*, 2000). This was recognised in the 2007 report by the Food Standard Agency's (FSA) Working Group on Variability and Uncertainty in Toxicology of Chemicals in Food, Consumer Products and the Environment (VUT):

> Ideally toxicity studies would be conducted in the animal species exhibiting toxicokinetics for the substance of interest that most closely resemble those in humans; however, in practice this is not always feasible, and rodents and a restricted range of other species are commonly used. This is based on availability and practicability and the existence of an extensive historical database. (Committee on Toxicity, 2007. 5.10 p.37)

This report, which feeds into the production of consumer food safety advice issued by the FSA, can clearly be seen to acknowledge that the choice of animals used as models in the risk assessment process is often determined on a pragmatic rather than scientific basis. This suggests that in such situations assumptions made by toxicologists are either: (1) that the choice of animal will not exhibit markedly different effects to the ideal, or (2) that risk management decisions taken at a later stage will adequately deal with species variation in the testing process, or (3) both are assumed.

The choice of species or even strain of species in which to undertake experimental toxicological research is critical as responses to chemical exposure may differ markedly between species and even strains of the

same species (Steinmetz *et al.*, 1998; Kloting *et al.*, 2003; Scholze and Kortenkamp, 2007). Such differences were frequently mentioned as problematic by interviewees. For example (K), a senior toxicologist from the Pesticide Safety Directorate (PSD) noted that known variation made it possible to choose a strain so that a particular effect was masked, or to choose a strain where there is a naturally large variation, so that any effect would be difficult to distinguish from the control group. (K) noted that this situation had the potential to be exploited to have a pesticide pass assessment:

> "if you think your compound is going to produce certain types of testicular tumours you could choose a rat strain that has a very high background…but there is also the potential that that particular strain has a very low background of other types of tumours so by trying to mask one you could end up allowing someone to pick something up that wouldn't have been quite so obvious in a different strain, I would hope that companies aren't quite that cynical but I wouldn't actually bet much of my pension on it," (K) Senior PSD Toxicologist

The above suggests that the choice of animal can affect the outcome of the test and introduce error into the risk assessment process. Additionally (X), a member of the ACP, suggested that the intensive inbreeding of rats for the purpose of toxicological testing has resulted in strains that in their opinion cannot be considered normal:

> “well everybody uses rats, and actually they are not necessarily very good, because these inbred strains can have funny little quirks of their own, I mean there is one inbred strain that routinely shows up quite large numbers of baby rats that only have one eye, and I think lets not use them at all, lets not even go down that route because obviously this is not a normal animal and not something you want,” (X) ACP Member

Such a statement questions the reliability of the data derived from the use of animals which are being routinely used as human models, yet cannot be seen as representative of a normal version of the species tested.

Importantly, in some areas there may be no animal equivalent for particular human illnesses or conditions, which either makes animal models redundant or requires the use of proxy indicators, which introduces a further layer of uncertainty into the assessment. An example of this in pesticide assessment can be seen in the study of developmental neurotoxicity (DNT), where although the majority of regulatory data are obtained from rodent studies, it is recognised within some scientific and advisory literature that there are limitations as “there is no age at which the whole rodent brain can be considered to be at a stage of development equivalent to the human” (Vidair, 2004; Committee on Toxicity, 2007 p.80 [9.28]). Additionally, the VUT report highlights that there is a debate surrounding the interpretation of results and whether tests are

sophisticated enough to observe a disturbance of particular modes of cognitive function:

> …observations could be interpreted as either a demonstration of the lack of neurotoxicity at low doses or the insensitivity of the regulatory tests to disturbance of higher cognitive function. (Committee on Toxicity, 2007, 9.29)

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has also discussed the interpretation of data in neurotoxicity studies with reference to the setting of ARfD for pesticides. Here it cites the example of the pesticide MPTP to highlight that negative results in an animal study do not always equate to negative effects in humans (Solecki *et al.*, 2005 p.1583). In such situations it suggests that the solution is to use the most sensitive species when deriving ARfDs. However, it is not clear how the most sensitive species should be identified or how prior knowledge should exist as to the fact that an effect will not exhibit in a particular animal.

5.33 Statistical robustness

A key consideration in experimental study design is the number of animals required. Typically, tests with animals are designed to be amenable to statistical analysis (Festing, 2000) and the tests required for regulatory purposes, such as those from the OECD (1993), offer guidelines on the minimum number of animals which should be used to ensure reliability. This is in part because the number of animals used can influence the LOAEL and the NOAEL, which can be defined as the lowest

observed adverse effect level that is significantly different from the untreated control group (LOAEL) and the no observed adverse effect level (NOAEL), which is typically the next lower tested group. This influence was discussed by (S), a member of the Committee on Toxicity (COT), who highlights how the number of animals used can be important in determining whether a response to a chemical can be treated as an effect:

> "the No Effect Dose sounds as if it is good because it says, *'well at this dose there is no effect, therefore it is safe'*, but all that actually means is, that with the size of the group we measured and the endpoint we measured, we could not distinguish between these animals and the controls, it does not actually mean that there was no effect" (S) COT Working Group Member

As detailed by (S), producing the LOAEL and NOAEL requires the use of statistical hypothesis testing, a process that can result in two types of errors: Type 1 where a false positive occurs, or the error of rejecting a correct null hypothesis and Type 2 where a false negative occurs, or the error of not rejecting a false null hypothesis. In addition, a third type is now thought of as being present. Type 3 errors relate to the framing of risk problems, the presence of ignorance and the inability of risk assessors to account for unknown variables and processes in their decision-making (De Marchi, 2003).

Errors are important considerations in regulatory science as the occurrence of Type 1 errors may to lead to over-regulation, which is likely to be expensive and over protective, while an excess of Type 2 errors is likely to lead to under-regulation, increasing the possibility of risk through exposure. Scientists are able to control the probability of a Type 1 error occurring through choosing an appropriate significance level (α), which is usually at least 0.5, which relates to a 95% confidence interval. Scholze and Kortenkamp (2007 p.85) highlight how the rates for Type 1 and 2 errors are inversely related, whereby the smaller the probability of one the larger the probability of the other, indicating that the use of a small (α) may lead to an increase in Type 2 errors.

The setting of appropriate significance values has important consequences as increasing an (α) value from 0.05 to 0.01 would require a greater difference between the control and dosed groups for the result to be considered as significant (Douglas, 2000). This would act to decrease the likelihood of Type 1 errors but lead to an increase in Type 2 errors. This may be important in rarer diseases or toxicological effects that have a low incidence rate in both the control and dosed group. In such a situation the detection of a potential risk is strongly linked to the confidence level chosen (Cranor, 1993).

Douglas (2000 p.566), in discussing "inductive risk"[43], suggests that in many circumstances the choice of statistical significance in risk

[43] Here Douglas (2000 p.561) uses Hempel's (1965) definition of "inductive risk", to state that "because no evidence can establish a hypothesis with certainty, acceptance (of a hypothesis) carries with it

assessment studies is not made on an understanding of mathematical theory, rather, it is guided through research tradition and/or more pragmatic factors such as the choice of statistical software that is to be used. Cranor (1993 p.33) too suggests that a low significance level value may be linked to a cultural philosophy regarding scientific progress and a demand for certainty:

> When the chances of false positives are kept low, a positive result can be added to scientific knowledge with considerable knowledge that it is not a random chance. Were one to tolerate higher risks of false positives, take greater chances of new information being false by chance alone, the edifice would be much less secure. (Cranor, 1993, p.33)

The above suggests that the requirements and constraints of toxicological testing for regulatory purposes can impact on the determination of the NOAEL and LOAEL, which in turn will affect the value of the reference dose. This point was acknowledged by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), who after an extensive review of pesticide risk assessment data found up to 2500-fold differences in the ARfD values set for individual pesticides as a result of different NOAEL and LOAEL values being used in calculations (Solecki *et al.*, 2005, p. 1572).

In addition to highlighting the importance of choosing the correct study to set regulatory guideline values, the differences re-illustrate how the

---

'inductive risk' that the hypothesis may turn out to be incorrect. Inductive risk is the risk of error in accepting or rejecting hypotheses".

selection of animals can greatly affect the outcome of toxicological tests. The JMPR's review also exemplifies how reference doses vary by country and are determined by social and political decisions as well as toxicological evidence. This situation was discussed by interviewee (P), an academic mixtures toxicologist, who spoke of attending a regulatory committee and being asked to vote on the most appropriate study from which to extract an NOAEL value. The example suggests that regulatory decisions remain reliant upon expert judgement and a degree of flexibility and discretion in the assessment process.

Despite the statistical requirements for certain numbers of animals to be used in regulatory tests, many interviewees made reference to the fact that they frequently see studies where only a small number of animals are used, a point that many found problematic. For example, (X), a member of the ACP, was concerned as to the statistical robustness of such studies:

> "I think one of the worries at the moment is that numbers of animals that are required to be used, I mean everyone is trying to reduce the levels of animal use, so the numbers of animals used I think are very very small, they are so tiny, you know they perhaps use five in each set or something like that, and you know if one of the animals has something funny wrong with it, it throws everything out," (X) ACP Member

(X)'s concerns raise questions about the utility of data produced with small sample sizes. For example, what benefit is to be gained from

conducting *in vivo* research if the results are not amenable to statistical analysis or effects cannot be statistically differentiated from the control group with the necessary degree of confidence for regulatory purposes?

The reduction in the numbers of animals being used is part of a move by European authorities towards alternative methods. This can be seen by the adoption of Directive 86/609/EEC in 1986, where a key aim was to reduce, refine or replace the numbers of animals used within experiments through stipulating that animal experiments should not be performed where alternative methods exist[44] (European Commission, 2008). However, many of the toxicologists I interviewed questioned the availability of alternative methods despite the Directive being implemented over 20 years ago.

For example, (D), a senior toxicologist at the Food Standards Agency (FSA), did not believe there would be an imminent reduction in animal use within regulatory tests, as they considered *in vitro* and other methods unable to replicate the complexity of a whole organism:

> "there is a lot of interest in the potential of toxicogenomics to cut down on animal testing, but that has quite a long way to go yet, not least because we need to understand more about

[44] The Directive prompted the creation of the European Centre for the Validation of Alternative Methods (ECVAM) in 1992. A similar centre was created in the UK known as the NC3Rs (National Centre for the Replacement, Refinement and Reduction of Animals in Research) which focuses on the "promotion, development and implementation of the 3Rs in animal research and testing" (NC3Rs, 2008).

> what various gene changes mean, but also you know the whole animal, or the whole human is a complex organism with systems as well as tissues and organs and it is very difficult to replicate" (D) Senior FSA Toxicologist

Similarly, toxicologist (L), a member of the ACP, commented that in their opinion there simply are not enough suitable *in vitro* tests to replace the *in vivo* studies stipulated in the regulatory guidelines.

While the above are generalisations, such comments do indicate a perception among the regulatory community that characterisation of hazard in the risk assessment of pesticides will remain reliant, at least in the near future, on the use of *in vivo* methods despite their acknowledged flaws.

5.34 Summary of regulatory pesticide toxicology

In the above I have illustrated that although *in vivo* testing is the dominant method employed in the toxicological assessment of pesticides it is not without its difficulties, many of which appear to be recognised to varying degrees by the scientific and regulatory community. Such difficulties include selecting a suitable animal model to mirror human development, replicating 'normal' growth in laboratory conditions where practical considerations may affect results, and selecting enough animals for the test to be statistically meaningful. I have argued that differences in strain response and abnormal development can be problematic for

regulators and risk assessors, and raise the question of how appropriate it is to extrapolate animal data to humans.

I have argued that despite a call for the most sensitive species to be used, animals are often selected on a pragmatic basis or because of historic regulatory norms. I have also discussed that the requirements and constraints of toxicological testing for regulatory purposes, which may be determined and shaped by social and political factors, impact on the determination of the NOAEL and LOAEL, which in turn will affect the value of the reference dose and whether a substance is considered acceptable for use.

What is interesting is that despite recognising many of these drawbacks, the regulatory community remains reliant on *in vivo* methods due to a perception within this community that there are few viable assessment alternatives. These observations support previous sociological research on the practice of risk assessment, such as that conducted by Wynne (1992), which suggests that knowledge of risk is often determined by pragmatic decisions based on practicalities such as what is measurable or observable.

The evidence also suggests that there is a culture within pesticide risk assessment that places emphasis on reducing the possibility of Type 1 errors (false positives) and hence avoiding over-regulation. This was shown to be problematic for rarer diseases or toxicological effects that have a low incidence rate in both the control and dosed group. The current lack of awareness of the third type of error in risk assessment

may also be problematic as it suggests that there is limited scope for wider thinking in the risk assessment process. This has tangible consequences in relation to risk assessment and risk management; the four stage risk assessment model, as illustrated by Defra, suggests that if an issue is not considered within the first three stages (hazard identification, hazard characterisation and exposure assessment) then it will ultimately be excluded in the characterisation of risk and in turn methods of risk management. The limitations discussed in this section therefore suggest that the characterisation of risk using data collected from *in vivo* methods is a proxy for the actual level of risk, which is indeterminable within the current system.

5.4 How are the challenges posed by exposure to mixtures and low-levels of pesticides addressed in risk assessment?

In the previous sections I have shown that even before one begins to consider the challenges posed by the problem of low-level exposure and chemical mixtures, risk assessment of pesticides is already characterised by significant uncertainties arising from the reliance on *in vivo* methodology that is mandated by current regulatory guidelines. I now turn to the area of risk assessment that addresses the issues presented by exposure to low-levels and mixtures of chemicals. As I have highlighted in Chapter One, there is now a growing body of literature which suggests current regulations and risk assessment practices do not adequately ensure that human health and the environment are protected from exposure to mixtures; where procedures are in place it has been

suggested in some scientific literature that there is likely to be a high degree of uncertainty (van Zorge, 1996; Weinhold, 2003; Wharfe *et al.*, 2004). Such uncertainty may in part be due to the amount of time and research that has historically been spent investigating this area; compared to the research investigating the adverse effects of single substances, exposure to chemical mixtures has received only marginal attention. This deficiency was highlighted by the IPCS (2001) in its framework for integrated risk assessment where it states that "many international and national organisations have expressed a need for an integrated, holistic approach to risk assessment that addresses real life situations of multichemical, multimedia and multispecies exposures".

Indeed, the Advisory Committee on Pesticides (ACP), recently issued a joint regulatory update on its approach to assessing the mammalian toxicity of two or more compounds when found in a single pesticide product (Pesticide Safety Directorate, 2005). This update highlights that while the ACP does now consider potential interactions of multiple active substances if present in one formulated product, there remain areas of known uncertainties for some active substance, such as the mechanism of mammalian toxicity (ibid, p. 2). However, the subject of assessing risk from a mixture of products is less clear, a point touched upon by ACP member (N), who suggested that this was an area in which the ACP lacked expertise:

> "I mean on this one at a time basis it [the ACP] does a thorough job in applying the law as it is now, however, there are some areas of uncertainty in the risk assessments which

> are done, and those are the ones that I am often banging a drum about, so one obviously is mixtures…we are not experts on that at all," (N) ACP Member

In the above, (N) reflects that the current practice of assessing chemicals on a single substance basis may not be sufficiently robust to protect the public from any risk posed by exposure to mixtures of pesticides. The use of the phrase "I am often banging a drum about" also suggests that N's concerns are either not shared across the Committee, or that mixtures are not routinely addressed in the ACP's evaluations of risk assessment data.

This issue has been discussed by the sociologist Casper (2003), who highlights that the study of the effect of chemicals on the environment and human health has been limited to a few highly contested and often contradictory examples of individual chemicals which have been modelled or tested using only known pathways, which often cannot replicate the complexity of real life exposure patterns. Although toxicological testing of individual chemicals is useful in predicting the fate and behaviour of a chemical in the environment, reality is more complex with chemicals occurring in combination at low-doses over long time periods. It is therefore often difficult and expensive to isolate the effect of exposure to mixtures from other factors. It is in part this complexity and the possibility for variance in the composition of mixtures that makes the assessment of risk challenging for regulators. Shore (2003), in her study on indoor air pollution, proposes that this has resulted in chemical mixtures being understudied and poorly understood by those considered

as expert. A view that appears to be supported in (N)'s comments above and shared by (P), an academic toxicologist specialising in mixtures, who too suggested that mixtures research had been marginalised due to a perception among regulators and scientists that both the science and the regulation of this issue was seen as too complicated. van Zorge (1996, p.1033) proposes that marginalisation has largely occurred for two reasons:

- The problem is regarded as too complex so solutions cannot be expected
- The problem is regarded as a non-problem at low levels of exposure (e.g. where health-based standards for components of the mixture are not exceeded. In this case standard setting for single substances is expected to be sufficient)

The issue of risk assessment of pesticide mixtures was publicly addressed by the Food Standards Agency (FSA) in 2000 when it set up the Working Group on Risk Assessment of Mixtures of Pesticides and Similar Substances (WiGRAMP). The report by WiGRAMP clearly acknowledges the complexity involved in the study of mixtures of pesticides stating: "risk assessment of any toxic effects of chemical mixtures is extremely difficult" (Committee on Toxicity, 2002b, p.7). Additionally, it highlighted that while there have been several other reports investigating the toxicity of mixtures; the majority have focussed on additivity studies with few exploring the possibility of synergism. This finding is echoed by El-Masri *et al.* (1997) and Kortenkamp (Committee on Toxicity, 2001) who state

that due to the complexity involved, where studies exist they will typically only use binary mixtures at relatively high doses with acute toxicities and endpoints; situations which do not reflect real life exposure. However, the attitude to mixtures research appears to be changing, with the subject rising in prominence over the last decade at both a national and European level[45].

In the above I have discussed that although challenges surrounding exposure to low-levels and mixtures of chemicals are acknowledged as a concern, they appear marginalised within the current assessment framework. The following section explores why this may have occurred within pesticide risk assessment.

5.41 Pesticide assessment as an exemplar

The most common theme among toxicologists interviewed was that exposure to low-levels of pesticides, either singularly or as a mixture, was not an issue that they saw as a concern. This opinion can be seen in extracts such as the one shown below from (F), a renowned toxicologist, who when asked what they considered to be the main concerns regarding pesticide residues in food replied:

> "I don't think there are any…well I would say that in terms of any other chemical grouping pesticides are the most thoroughly studied and intensively evaluated group of

[45] See the European White Paper on a strategy for future chemicals policy (Commission of the European Communities, 2001).

> compounds by far, you know it is almost impossible to get a waiver for any component of the dossier" (F) COT Working Group Member

Here, framing the risk from pesticide residues as a non-issue (F) effectively denies legitimacy to any alternative view. This perspective may be explained through consideration of (F)'s status as an expert who has been deeply embedded in the regulation of pesticides and production of risk advice within the UK for the past twenty years. Therefore, if (F) were to acknowledge concern, they would be undermining the current risk assessment system by suggesting that it is somehow inadequate at protecting people's health and so unfit for purpose.

The framing of pesticide residues as a non-issue is again seen within former ACP member (I)'s dialogue:

> "as currently managed the risks from pesticide residues in food are substantially less than other health risks associated with food, for example risks from microbial food contamination and bird flu, risks relating to under and over nutrition…I think the evidence that we have on adverse health effects is that they occur principally in relation to use or misuse of pesticides rather than in relation to pesticide residues in the diet," (I) Former ACP Member

Here, (I) frames the risk from residues in relation to other food risks that (I) deems to be more pressing, thereby suggesting that this particular

risk is small. The relative insignificance is further implied through (I)'s framing of the risk in terms of pesticide 'misuse', ergo if rules are adhered to then risk is minimised or eliminated. A similar message can be seen in the following extract from ACP member (X), who, in speaking about bystander exposure, suggests that when problems occur, they do so due to human error:

> "I think the bystander effect is a very difficult one, I do think you can get problems when occasionally farmers misjudge it, they do overspray by mistake…I think you can genuinely get cases where frankly people have got the mix wrong…I mean given that a lot of people who are doing the spraying are not necessarily terribly good at maths or not terribly well educated, probably you could make it simpler," (X) ACP Member

As the above examples indicate, the overall consensus among interviewees from government bodies and in particular the ACP was that when compared to other chemical groups, pesticides are one of the most thoroughly and intensively tested group of all chemical compounds. Several interviewees referred to the fact that testing of pesticides has occurred in various guises for the past 40 to 50 years, which has resulted in a wealth of evidence surrounding their use and effect that simply is not there for other chemical groups; a factor that they used to justify their position that exposure to low-levels of pesticides such as residues in food was a non-issue.

This mass collection of data was attributed to the strict legal requirements that dictate the type of evidence that is required before a pesticide can be assessed for sale and use. Indeed, the scale of data collection led several advisory body interviewees to present pesticides as an exemplar of how other chemicals should be assessed.

Yet, whilst there is little doubt that the regulatory guidelines set out in Directive 91/414/EEC have increased the overall volume of data required for the assessment of new products, some interviewees, mostly NGO staff but also a senior Pesticide Safety Directorate (PSD) toxicologist, questioned what is actually being produced and whether the evidence stipulated by the regulatory risk assessment guidelines addresses the more complex and understudied areas such as the effects of exposure to mixtures. Indeed, while the majority of interviewees argued that the information requirements are designed to be comprehensive and that strict adherence is necessary to standardise data packages, others have expressed concerns that they are overly limiting and have led to a *"tick box"* mentality which acts to discourage the use of innovative techniques and restricts lateral thinking.

5.42 Is the method validated and has the box been ticked?

A key issue, as can be seen in the following quote from a senior toxicologist at the PSD, is that although regulatory bodies may be interested in a variety of assessment evidence they are in fact limited by regulatory requirements as to what they can officially use in practice:

> "I think that we are quite open to looking at the results but whether we can use them in a regulatory context is, to an extent we are restricted by the fact that we are supposed to be having studies done to these OECD guidelines, so if someone has got a new study which they think is equivalent to an OECD guideline study but has not gone through the process and been validated, whilst we can say yes this is very interesting and it sort of supports your argument, there can be legal or if you like regulatory questions over whether we can use it on its own without anything else to go with it" (K) Senior PSD Toxicologist

Similarly, (B), a science policy advisor for the Food Standards Agency (FSA), spoke of an evidence hierarchy, where evidence is weighted by its origin. So, (B) claims that the FSA considers evidence (of which science may be just one part) from all reputable sources, but that anecdotal evidence or evidence that had not been produced using validated methods was likely to be used as a starting point to guide future research, rather than evidence in itself. The reluctance of government advisory bodies to include alternative forms of evidence in assessments led several interviewees to comment that the necessity of adhering to guidelines can deter companies from developing and using newer methods, or collecting and submitting information outside of what is required, especially if there is no financial incentive to do so:

> "Well you could say that they should be upgrading and looking at newer methods…they don't because it is not required, you

> see they do the standard tests which are required, which everyone has settled on, which have been you know ECVAM validated or validated by time sort of thing…I mean why should they you see? It is going to cost money if they do research like that, and why should they? They are not asked to do it," (X) ACP Member

When asked about this issue, (R), a regulatory affairs manager for a pesticide manufacturer, suggested that there is a desire among industry to develop new tests but that this process can be frustrating as the resulting evidence will often not be counted in assessment; regulators are reluctant to use the resulting evidence due to concerns about the potential for litigation if a chemical was later found to cause harm.

However, the strict practices and closed nature of regulatory toxicology appear to be at odds with the depictions of the science of toxicology provided by interviewees, who described the field of toxicology as a "developing science" and stressed the importance of "thinking outside of the box". For example, toxicologist (S) illustrates the contradiction and tension that typifies the collection and assessment of pesticide data for regulatory purposes; that while standardisation is viewed as necessary to produce robust and acceptable evidence, "people have discovered toxic effects by applying cutting edge science using completely non-standard techniques, and it is important that they are allowed to do that and they are not limited by things being too standardised". This is likely to be important in areas such as the study of the effects of chronic exposure to

low-levels and mixtures, where current research may be being conducted using newer non-validated tests.

Several interviewees highlighted how the current regulatory evidence requirements have been shaped by historical scientific developments that saw a rise in the number and types of experiments that were available, thus suggesting that there are periods of transition, or paradigm shifts, in regulatory toxicology where the merits of older techniques are reviewed and newer methods become standardised, accepted for regulatory use and added to the battery of required tests. This idea was highlighted by (F), a member of the Committee on Toxicity (COT), who spoke of "going along with a paradigm that has been established by experience and practice".

While several interviewees felt that working within a paradigm offered advantages in relation to standardisation and robustness in assessment, others such as (K) felt that it has led to the development of a tick box mentality. (K), a PSD toxicologist, suggested that in the past when there were fewer guidelines, those producing evidence had to give greater thought to what they were doing. (K) discussed that the current routinisation of studies has resulted in a tick box approach where companies run through the required list of tests with little thought as to whether they are necessary or useful:

> "I would say using your brain more, you do a couple of studies and you say well we are not seeing anything in those so it is not worth doing that one and we should be looking over here,

> instead at the moment I think there is a lot of tick boxing, that you have to do these 30 studies and almost the companies just run through them and they don't really think about it, I think there should be more thought going in" (K) Senior PSD Toxicologist

The lack of consideration of wider consequences and the wasted potential for a greater use of the evidence was discussed by several interviewees. For example, (V), a British Crop Production Council (BCPC) representative, commented that they were aware of several people over the past 50 years who had wanted to pull all the evidence together and view it as a collective whole, but had been put off "by the enormity of the task". Likewise, (J), a toxicologist and member of a COT working group, believed that "the taking of a broad scientific view is less common in the pesticide world than in other worlds" such as medicine.

Unsurprisingly, this perceived lack of a wider perspective is heavily criticised by several NGOs and academics outside of the advisory bodies to be detrimental for the understanding of the issue as a whole. For example, interviewee (Y), a member of the Pesticide Action Network (PAN), highlighted the work of Theo Colborn[46] to illustrate how it was only when evidence from different scientific disciplines was brought together

[46] Theo Colborn, a zoologist and senior scientist with the WWF, co-wrote the book "Our Stolen Future" (Colborn *et al.*, 1997), which is widely viewed as a sequel to Carson's "Silent Spring" (Carson, 1962). The book outlines Colborn's work investigating the link between exposure to synthetic chemicals and endocrine disruption in wildlife and humans.

and considered holistically did the scientific community begin to realise that certain synthetic chemicals, including pesticides, were linked to endocrine disruption.

5.43 The problem of proving a negative

The limitations of collecting evidence surrounding the effects of pesticides in real life situations was also a recurring theme found in interviews with those working in pesticide regulation. This was summarised by (V), a representative from the British Crop Production Council (BCPC), who stated "one of the problems with pesticide residues or with pesticide regulatory science is that you are always trying to prove a negative, it is impossible isn't it?" Here (V) identifies a key issue; it is impossible to produce evidence to show that a substance is risk free in all situations. As such, decisions must be taken on the basis of available evidence, which at times, may not be comprehensive, particularly in those areas considered as fringe, such as chronic effects from the exposure to low-levels of mixtures. This was discussed by (S), a member of the Committee on Toxicity (COT), who stated: "essentially the issues that confront regulatory toxicologists are issues of how to prioritise the many different problems and where to stop the investigation, because resources are never going to be adequate to completely eliminate all potential forms of toxicity for all potential chemicals".

(S)'s statement suggests that risk assessors focus on those problems that they consider to be most concerning, suggesting that the choice of where and how to concentrate assessment is not purely scientific, but involves

judgement and social values. The use of framing in conceptualising risk problems therefore introduces the possibility of Type 3 errors occurring, i.e., the presence of 'ignorance' and the inability of risk assessors to account for unknown variables and processes in their decision-making. Hoffmann-Reim and Wynne (2002) discuss Type 3 errors in their article "In risk assessment, one has to admit ignorance", where they make the following bold statement (p.416): "Risk assessment and policy need to emphasize uncovering the limits to knowledge rather than proving existing knowledge to be correct."

A common theme seen in the interviews, especially with those from the Advisory Committee on Pesticides (ACP), was that in cases where links between exposure and effect are inconclusive, there was a tendency to flag up potential flaws in the research to justify the position that pesticides were a non-issue when used correctly. This can be seen in the excerpt below where ACP toxicologist (X), explains why, in their opinion, there is a lack of reliable evidence demonstrating a clear link between exposure to pesticides and cancer:

> "despite people really working very hard, I don't know of any evidence, at least for pesticides, which clearly links pesticide use with cancer, and there have been suggestions but in every case the research is flawed or you can think of a lot of other possibilities, so you know it might not be a pesticide at all," (X) ACP Member

(X)'s account is a classic example of what Gilbert and Mulkay (1984) describe as a contingent repertoire; a pattern of discourse frequently used by scientists to reduce the credibility of research or other scientists with whom they disagree. Here, the suggested lack of a clear link was used by (X) to justify not taking a more precautionary attitude towards pesticide use and regulation. A similar argument was made by (V) from the British Crop Production Council, who suggests that difficulties associated with epidemiology – "there is no hard and fast causal link you know, a lot of these seem to be coming from these epidemiological studies, which you know sometimes the numbers are a bit iffy as well" - are a reason why certain studies cannot be trusted or used for regulatory purposes.

However, this position of dismissing effects due to the inability to obtain water tight proof of causation was criticised by others interviewed, who suggested that such a position is misguided and being used to justify inaction. For example, (E), a former chairman of the Royal Commission on Environmental Pollution (RCEP), was vehement in stating that they believed "it highly probable that 90% of the areas where chemicals in the general sense and pesticides in particular are used, you will never be able to get any convincing statistics, and if you don't realise that to begin with, then I think there is a fundamental misunderstanding".

(E) went further in stating that although it can be difficult for a body charged with assessing evidence to publicly admit that there are areas of uncertainty, it is better to disclose ignorance than mask or avoid the problem - a practice that (E) suggests is common within the ACP:

> "if you say you don't know it is quite difficult, but I think we have now gone through a cultural change in most places apart from the ACP, where if you don't know, you say you don't know, because in the long run it is damaging to people and the community and it is even damaging to people's careers if you keep being dogmatic," (E) Former RCEP Chairman

(E)'s comments have obvious consequences in terms of the acceptability of evidence to regulatory authorities and advisory bodies. In particular, they suggest that the ACP does not recognise the limits in extrapolating data. The result of which is that the ACP is unable to acknowledge the potential uncertainty surrounding effects of human exposure to pesticides due to an unwillingness to acknowledge adverse effects, unless they can be conclusively proven. This view was shared by some dissenting members of the ACP, such as (O), who stated: "I do think that people, any individuals who think that their health has been damaged by pesticides should be listened to, and I think that they are too easily dismissed on the Committee [ACP]".

(E)'s suggestion that real life causal data are highly difficult to obtain was mirrored by others, in particular those interviewees who were members of NGOs, as can be seen in the following statement made by (Y), a staff member of the Pesticide Action Network (PAN):

> "there is so much uncertainty and there will be for the foreseeable future, particularly about chronic effects of pesticides that you therefore have to make a value judgement

> about where you think, how far you should take a precautionary approach," (Y) PAN Staff Member

Interviewee (C) from the Soil Association too raised concerns surrounding the extent to which the ACP recognises the limits of science and suggested that the ACP's mandate and embedded culture of simply assessing the science in isolation has meant that it often fails to consider the wider implications of pesticide use and agricultural practice:

> "you see it is the people who on the [ACP] who are lost in it, they are lost in this world of looking at detail and trying to, and not actually understanding the limits of science and thinking about whether pesticides are necessary," (C) Soil Association Staff Member

The key questions that these quotes raise were surmised by interviewee (E) who asked: "if you think then that there is no way of proving your case, should you act?" It is clear from the above that a lack of certainty in causation is often used as a reason by the Advisory Committee on Pesticides to justify maintaining the status quo and denying the need to invoke a more precautionary attitude in relation to pesticide use and exposure

5.5 Summary

Despite the commercial application of pesticides over the past sixty years there remain uncertainties surrounding their effects on human health and

the environment. In this chapter, I stepped behind the regulations to explore the toxicological science upon which pesticide reference doses, and hence risk advice, is derived. I illustrate that the regulatory assessment requirements, which are specific to pesticides, are now largely determined at a European level, although they remain managed within the UK by the Pesticide Safety Directorate (PSD) and the Advisory Committee on Pesticides (ACP). I discuss how within the UK it is the ACP who has responsibility for reviewing pesticide dossiers submitted by industry and that typically as a result of historical practice, pesticide substances are assessed on an individual basis so that potential effects from exposure to multiple pesticides are not routinely addressed within the risk assessment process. The result of which is that potential effects of exposure to mixtures are effectively excluded from ACP discussions and therefore remain formally unacknowledged in its assessment of risk.

For the purpose of this thesis I largely focus on the second stage of risk assessment, hazard characterisation and illustrate how there has historically been a reliance on *in vivo* methodology. I examine the tensions of this reliance and highlight that although those working in the area perceive there to be significant benefits in animal use, especially in trying to establish causality between dose, exposure and effect there are also recognised challenges. In particular, there are long standing concerns noted in both the scientific and policy literature regarding the appropriateness of using animals as a surrogate model for humans. These concerns centre on the validity of extrapolating effects observed or not observed in animals to humans. I discuss how the results of tests could be influenced by factors such as choice of animal species and

experimental design so that the very models used to expand our knowledge and understanding can themselves become a source of uncertainty. Importantly, I show that methodological choice is often made on the basis of social/community norms and pragmatic reasoning. In this sense, the methods and guidelines which have been put into place to standardise tests can be seen as introducing a false sense of confidence in the results as we remain ignorant of the true risk or scale of uncertainty. This finding supports previous research, such as that undertaken by Wynne and Mayer (1993), which has argued that the assessment of risk is itself subject to scientific uncertainty and that knowledge of risk is often determined by pragmatic decisions based on practicalities such as what is measurable or observable (Wynne, 1992).

Importantly, I use the interview and documentary evidence to suggest that there is a culture within pesticide risk assessment that encourages the reduction of Type 1 errors to avoid the possibility of over-regulation. I also suggest that there is both a lack of awareness and lack of scope in the current system to consider Type 3 errors. I argue that this and the reliance on animal testing in toxicology will have tangible consequences as it suggests that the current narrow characterisation of risk using data primarily collected from *in vivo* methods can only be a proxy for the actual level of risk, which is currently indeterminable.

When considering the previous ad hoc nature of pesticide assessment, the move towards standardised methods and guidelines is viewed by many in the field as positive; if applied consistently across Europe it should provide a baseline of data which are transferable across countries and

markets. This can be crucially important for regulatory agencies and assessment bodies who may have limited resources and time in which to make decisions. Mandating evidence requirements should in theory ensure that every substance is assessed on equal grounds and using the most useful and appropriate information. However, the evidence presented here suggests that standardisation can equally have the effect of devaluing evidence which is produced outside of this process and limiting its scope to impact on decision making – assessment bodies are simply not able to consider it, as it is classed as unacceptable or unfit for regulatory purposes.

I argued that this is likely to be problematic in those areas, such as mixtures toxicology, which often utilise newer alternative non-validated methods. Additionally, it was noted that although working within an established paradigm was believed by interviewees to offer advantages, the very methods adopted to increase our understanding through providing a strong evidence base, were also recognised by some interviewees as barriers to developing new knowledge. I show that there is a belief among some regulatory toxicologists that the current routinisation of studies has resulted in a tick box mentality which discourages consideration of both new approaches and areas outside of the regulatory remit. Thus the evidence presented here indicates that there is a tension present in pesticide regulatory science; although it is widely acknowledged that standardisation and routine are required to produce robust regulatory evidence, it is often only when toxicologists are able to think creatively and apply non-standard techniques that understanding is increased.

It is also clear from this evidence that the decisions as to how tests are designed and selected for use in determining human reference doses are not wholly objective as is often purported but are intrinsically shaped by historical, social and pragmatic considerations regarding what is actually measurable. The very fact that methods differ across countries suggests that assessment and interpretation of results is in part a political and value based activity. In this sense the findings of this thesis support previous STS arguments, such as those made by Irwin *et al.* (1997, p. 24), that suggest because risk assessment guidelines have been shaped by social objectives, the underlying science can never be truly separated from social values. Thus, to quote the authors (ibid); the science used in pesticide regulatory risk assessment "interlinks social, bureaucratic and scientific demands" with the result that social assumptions are allowed to "pervade the development of a technical regulatory regime".

A recurring theme found in interviews with those working within pesticide regulation related to the limitations in obtaining evidence pertaining to the effects of pesticides in real life situations. Therefore, decisions have to be taken in the knowledge that there is a degree of uncertainty. However, I discuss that there is a perception - primarily among those outside of the ACP and the government advisory process, but it is also one recognised and shared by the RCEP - that the Advisory Committee on Pesticides (ACP) is reluctant to acknowledge this uncertainty in its decision-making process. I use the evidence collected in this thesis to further suggest that lack of certainty in studies exploring causation between real life exposure and ill health are used by the ACP as an argument to maintain the status quo and current regulatory practices. Shackley and Wynne's (1996)

examination of boundary-ordering devices, suggests that scientific uncertainty can challenge both science and the authority of scientists. If applied here, it suggests that the ACP may deny the possibility of uncertainty in its assessments so as not to undermine the current regulatory system, within which it is embedded.

In the later part of the chapter I show that a key area of challenge and uncertainty in pesticide risk assessment is in how to study and assess chemical mixtures. Drawing on both published literature (van Zorge, 1996; IPCS, 2001; Shore, 2003) and interview data I suggest that this area has historically received limited attention within the regulatory and risk advisory community for two reasons: first, there is a perception among regulators and scientists that the science is difficult to conduct and that the area is too complex to regulate; secondly, there is a belief that exposure to mixtures is a non-issue when individual components are present at otherwise acceptable levels. Where mixtures have been considered I show that researchers have typically favoured undertaking simple studies, for example using binary mixtures at high doses. In doing so the complexity found in real life exposure is likely to be reduced. This would suggest that within the current risk assessment paradigm the true scale of uncertainty regarding the risks from exposure to mixtures is indeterminable.

The case of assessing pesticide mixtures therefore supports Wynne's (1992) argument that the pervasion of pragmatic choices in toxicological studies has the effect of artificially reducing uncertainty. A key problem of this action, as noted by Wynne (ibid), is that once uncertainty has been

removed it becomes difficult to reintroduce at a later stage of assessment and analysis.

Chapter 6: Fragmentation of Government Advice on Pesticide Risks

6.1 Introduction

In previous chapters I have suggested that despite scientific developments, the uncertainties present and the questions that are being asked about the risks of pesticides have not significantly altered since the first consumer review in 1953. In Chapter Five I argued that both the means of production and presentation of scientific evidence for regulation can be implicitly and explicitly shaped by social, political and pragmatic factors, such as regulatory guidelines and historic scientific norms. This chapter focuses on risk advice, the stage following risk assessment, and highlights how institutional practices can act not only as frames and boundary objects that help establish which areas of risk are seen as most important, but can also determine which evidence is acceptable for use in providing advice.

In this chapter, I examine the key emerging tensions found between the official advisory system for pesticide regulation, as typified by the Advisory Committee on Pesticides (ACP), and other government bodies involved in assessing risk and providing advice, with specific reference to how these conflicts have been managed. To achieve this I draw on three case studies. First, I examine the 2002 report produced by the Working Group on the Risk Assessment of Mixtures of Pesticides which, although concluding that the risk from exposure to mixtures is likely to be small, posed challenges to the risk assessment practices of the ACP. Second, I

examine the advice from the Food Standards Agency (FSA) surrounding the consumption of pesticide residues and how initial advice was subsequently altered in line with the ACP's recommendations. Third, I consider the 2005 report produced by the Royal Commission on Environmental Pollution (RCEP) entitled "Crop Spraying and the Health of Residents and Bystanders", whose precautionary recommendations provoked widespread criticism across other government advisory bodies, such as the ACP and the Committee on Toxicity (COT).

6.11 Risk advice

Risk advice is a heterogeneous term that varies in meaning depending on context and user. In this thesis the term is used to describe the provision of recommendations that are meant to aid decision-making that might reduce or prevent the occurrence of harm. To be effective, risk advice needs to be seen as grounded in clear evidence or philosophy, it has to appeal on either the basis of facts and known outcomes, or it must conform to a set of shared social values. In recent years, following the controversy over the link between BSE in cattle and vCJD in humans, the UK Government has emphasised its use of evidence-based decision-making in the creation of official risk advice (The Cabinet Office, 1999; The Strategy Unit, 2002), suggesting that government advice is based on identifiable evidence, as opposed to political or social values.

The production and provision of risk advice is commonly associated with guidelines and recommendations provided by governmental bodies. However, it is recognised that there has been a proliferation of risk advice

in recent years surrounding use and exposure to pesticides with the effect that government can no longer be considered the sole provider; advice is now easily obtainable from a range of sources including foreign regulatory authorities and NGOs (The Strategy Unit, 2002. p.22). Additionally, as different aspects of pesticides have been allocated to different advisory areas – see Chapter Four – there has been a fragmentation of advice provision within government. While the greater provision of advice should not in itself be problematic, it may become so if advice differs by source or is contradictory in nature. It is therefore important to explore how different groups of information providers produce their risk advice and why advice can vary, even between government advisory bodies when all are claiming to ground their advice in evidence.

To select evidence to use in both risk assessment and risk advice it is first necessary to define the problem that requires solving. Previous chapters have illustrated that the area of risk relating to pesticide exposure is complex and entrenched in wider concerns surrounding the environment and human health. In situations where questions and problems associated with risk are difficult to single out, it often becomes necessary to invoke a selective vision, where issues are framed to make them manageable or controllable (Jasanoff, 2000; Millstone, 2007). The development and invocation of regulatory and advisory remits can therefore be viewed as one method of framing.

In addition to helping define the problems posed in risk assessment, framing determines what evidence is and is not acceptable in risk discussions and how such evidence is interpreted, a consequence of which

is that those who are not able to present acceptable evidence are effectively excluded from actively participating in any risk dialogue.

In this chapter I use three case studies to illustrate how there are now not only tensions between government and environmental groups, but also tension between and within different government bodies as advice becomes more fragmented. I suggest that such tension is the result of conflicting political remits, which has resulted in differing conceptualisations of scientific uncertainty and a public struggle to gain authority in an increasingly overcrowded advisory area. In all examples, I discuss how the risk assessment practices and advice produced by the Advisory Committee on Pesticides (ACP) has been challenged, and how in all cases the ACP has successfully managed to set aside concerns and maintain the status quo through exerting its institutional authority in this domain.

6.2 Advice on exposure to pesticide mixtures

The first case study explores the Working Group on the Risk Assessment of Mixtures of Pesticides (WiGRAMP)[47] and its 2002 report entitled "Risk Assessment of Mixtures of Pesticides and Similar Substances", which was published at the request of the Food Standards Agency (FSA) by the Committee on Toxicity (Committee on Toxicity, 2002b). Since publication,

[47] The WiGRAMP was a working group set up by the Committee on Toxicity. The WiGARMP had ten members, which included those with expertise in medicine, toxicology, biostatistics, pathology and pharmacology. There were also two public interest members (Committee on Toxicity, 2002b).

this report has become a key document that is used by the FSA to issue consumer advice regarding exposure to mixtures of pesticides through the consumption of residues in food. The report is the culmination of a review of scientific and policy documents, and evidence presented to the WiGRAMP from those it considered as experts and stakeholder groups.

The establishment of the WiGRAMP appears to have been driven by social demands, rather than any significant changes to the scientific understanding of mixtures. This can be seen in the report's introduction, where it is stated that it was a combination of consumer concern and a statement by the outgoing Chairman of the Working Party on Pesticide Residues (WPPR) in 1999[48] that prompted the FSA to ask the COT to establish a working group to review the risk assessment of pesticide mixtures. At the beginning of the executive summary it is reported that there is a recognised concern[49] "that the regulatory system for pesticides found in foods does not routinely address the toxic effects of different substances in combination" (Committee on Toxicity, 2002b, p. 5). This was followed by an acknowledgement that to date, no information has

[48] The report states that the outgoing Chairman of the WPPR "drew attention to the fact that little is know about the toxicological interactions between pesticides and commented "that pesticide residues of the same class (for example organophosphates) will be at least additive in their effects because they act by the same toxicological mechanism"" (Committee on Toxicity, 2002b, p.11).

[49] The report at this point does not indicate the source of concern. However, in 2.7 the report states that the Working Group reviewed information regarding "concerns which have been expressed by consumers and other stakeholders" (Committee on Toxicity, 2002b, p. 12).

been specifically reviewed regarding the effects of exposure to mixtures of pesticides in the UK, and that "until this has been done, it cannot be judged whether the approach currently taken to risk assessment is sufficiently protective and based on sound toxicological principles" (ibid, p.11). In particular, like others discussed in Chapter Five, the WiGRAMP drew attention to the fact that existing research, which has focussed on the interaction effects at high doses, may be unsuitable for use in the assessment of exposure to the non-toxic levels found in food items.

Towards the beginning of the report the WiGRAMP acknowledges a number of limitations and difficulties associated with assessing the toxicology of mixtures – see paragraphs 1.14 – 1.19 (ibid). Within these paragraphs the Working Group details that the "risk assessment of any toxic effects of chemical mixtures is extremely difficult" and that "some interactions may not be easy to predict". However, it is stated that not only are there "relatively few" studies available that consider the effects of mixtures, but that "for the most part" the studies are not appropriate for use. The report further states that those studies that the Working Group did consider to be well designed are probably unrepresentative of exposure dose. This can be seen as a bold statement considering paragraph 1.11 of the same report:

> The committee considered that because of the nature of the pesticide and veterinary surveillance programmes, it was extremely difficult to assess the frequency with which residues, below or above legally enforceable maximum residue limits (MRLs) occur…Further, data on exposure from sources

> other than food and water seem to be extremely scanty or non-existent. (Committee on Toxicity, 2002b)

These statements suggest that within an already relatively narrow sphere of research and literature, the WiGRAMP further limited the evidence it considered as acceptable for use in this review. It is unclear from the report what criteria the WiGRAMP applied when deciding to include or reject data. However, in Chapter Five it is suggested that it is usual for government bodies to apply a strict framework regarding evidence selection as they are often limited by externally imposed regulatory requirements and guidelines.

Following a two year review the Working Group made several recommendations regarding future assessment and approval of pesticides – see Box One. These recommendations suggest that there were areas of the current risk assessment process, as used by the ACP, which could be improved upon or further developed in respect of assessing and managing mixtures. Notably, it proposes that there should be additional "formal analysis and possible experimental investigation" to assess the risks posed by mixtures, which it suggests will require changes to the methodology currently employed. However, despite all of these recommendations and the clear acknowledgement of uncertainty, the central finding of the report, which has been repeatedly used by the FSA in its risk advice, is that "the risk to people's health from mixtures of residues is likely to be small". Given all of the above this finding has been widely criticised and challenged by scientists and NGO groups alike.

Box 1: Regulatory Recommendations taken from the Executive Summary of the WiGRAMP Report (Committee on Toxicity, 2002b)

1.24 We recommend that the approval of pesticides used on crops, and authorization of similar compounds used in veterinary medicine should consider all sources of exposure.

1.25 We recommend that a scientific and systematic framework should be established to decide when it is appropriate to carry out combined risk assessments of exposures to more than one pesticide and/or veterinary medicine.

1.26 In the event that it is considered appropriate to carry out risk assessment of combined exposure, the default assumptions should be that chemicals with different toxic actions will act independently (simple dissimilar action), and those with the same toxic action will act additively (simple similar action). In the latter circumstances a toxic equivalency approach might be considered. In specific instances the possibility of interaction, particularly of potentiation, may have to be considered. In such circumstances adequate dose-response data will be essential in the interpretation of findings in relation to dietary intakes and other human exposures.

1.27 We recommend that the approval of pesticides and authorization of compounds used in veterinary medicine should include more formal analysis, and possibly experimental investigation, of the potential for combined toxic action or interaction due to the addition of other substances to the formulations employed. This consideration should also include tank mixes of pesticides.

1.28 Analysis of all sources of exposure to pesticides and of concurrent exposure to more than one pesticide will require changes in the methods used in risk assessment, including, in some cases, the use of probabilistic exposure assessment. This will be contingent on changes in residue surveillance.

6.21 Criticism of the WiGRAMP report

The publication of the report resulted in much criticism towards the WiGRAMP. Interestingly, this criticism varied from suggestions that the report failed to fully acknowledge the uncertainty and public concerns, to suggestions that it was overly alarmist in presenting pesticides as universally bad, while at the same time being over critical of the ACP and the current risk assessment methods.

Prior to the final publication, a draft report was made available for consultation – Box Two details part of the draft Executive Summary. To understand the type of criticisms levelled at the WiGRAMP I have drawn on interview data from those working in this area at the time of consultation and publication, and examined examples of the correspondence received during this period. It should be noted that the original correspondence was unavailable for viewing and that the extracts shown here originate from the sender, as opposed to the Food Standards Agency where this information is stored. However, having discussed the type of responses received with those within the WiGRAMP, the evidence presented here appears to be reflective of the range of responses it received.

The first piece of correspondence to be examined is from Professor Andreas Kortenkamp, a prominent UK based toxicologist who specialises in studying multi-component mixtures. Kortenkamp wrote to the WiGRAMP expressing concerns regarding both the report's findings and the conceptual understanding of the Working Group, which he viewed as lacking in the area of mixtures toxicology.

Box 2: Executive Summary of the Draft WiGRAMP Report 1.20 – 1.23 (Committee on Toxicity, 2002a)

Implications for assessing potential health risks for humans exposed to pesticide mixtures

1.20 Generally, when exposure levels of the chemicals within a mixture are in the range of the NOAELs, no additivity and no potentiating interactions are found, indicating the applicability of the basic concept of "simple dissimilar action", which suggests that adverse reactions would be unlikely.

1.21 On the other hand, in vivo studies with chemicals that exhibit the same target organ and the same mode of action have shown that the effects of mixtures of similarly acting toxicants show additivity (dose addition), which results from simple similar action. This is the case, even at levels slightly below the LOAEL of the individual compounds. The dose addition model is applicable over the range of exposure levels up to and above NOAELs.

1.22 Some studies (acute and subacute toxicity, genetic toxicity, carcinogenicity) have addressed the combined effect of mixtures of pesticides and in a few studies clear cases of potentiation were observed in animals exposed to levels of toxic substances showing adverse effects of individual compounds. However, direct extrapolation of these findings to much lower dose levels is not valid. Thus the probability of any health hazard due to additivity or potentiating interaction of mixtures at (low) non-toxic doses of the individual chemicals is likely to be small, since the dose of pesticides to which humans are exposed is generally much lower than the NOAEL, at least through food.

1.23 Some endpoints that have been studied in animals or in in vitro systems are relevant to groups in the population believed to be at higher risk than the general population. Such endpoints include developmental toxicity studies, endocrine and neurotoxic effects and genotoxicity studies. On the basis of limited information it seems likely that the default assumptions in relation to mixtures in children and pregnant and nursing mothers would be the same as for the rest of the population.

In particular, Kortenkamp appears concerned with the statements made by the WiGRAMP in paragraphs 1.20 and 1.21 of the Executive Summary (Box Two), which suggests exposure to mixtures is unlikely to result in adverse reactions when individual components are present at levels similar to the No Observed Adverse Effect Level (NOAEL); a view that is common among regulators – see Chapter Five. The extract below is taken from Kortenkamp's letter (sic):

> This statement is misleading…It seems to me that, throughout the draft report, the Working Group has erroneously equated NOAEL with NEL. To clarify the resulting ambiguities, the report will gain from taking account of a current debate concerning the inappropriateness of NOEL as estimates of low (toxic) effects. With many toxicological tests, effects below 10% cannot usually be detected as significantly different from untreated controls. The level of sensitivity is often anywhere between 10 and 30%....In other words, the poorer the data quality, the larger the NOEL. Thus, NOEL (and NOAEL) are quite unreliable estimates of zero effect levels. Rather, they define a range of doses where the occurrence of effects can neither be ruled out, nor confirmed. This is something altogether different from NEL! Thus, the above statement [1.20] is only correct when NOAEL is replaced with NEL. Similar considerations apply to this paragraph [1.21]. It contains the sentence: **"This** (i.e. dose addition, AK) **is the case, even at levels slightly below the LOAEL of the individual compounds".** This time, the Working Group

> appears to confuse NEL with LOAEL. Dose addition will occur, even at levels below zero effect levels, provided the number of mixture components is sufficiently large. (Kortenkamp, 2002)

In this excerpt Kortenkamp highlights that the phrasing of the draft statement erroneously equates the No Observed Effect Level (NOEL), the NOAEL and at times the Lowest Observed Adverse Effect Level (LOAEL) with the No Effect Level (NEL). This makes the statement misleading as the NEL, the most stringent standard, suggests the lowest risk. Kortenkamp's criticisms appear to have been noted by WiGRAMP as the wording of 1.20 and 1.21 was altered in the final document – see Box Three.

Specifically, paragraph 1.20 has been significantly altered with the final version making no reference to NOAELs, the possibility of potentiation or the possibility of an adverse effect occurring. Although paragraph 1.20 in the draft report begins with 'generally', the proceeding statement, with the clear use of the word 'no', suggested the WiGRAMP was confident that "simple dissimilar action"[50] is the most suitable concept for use and as a result exposure to mixtures is 'unlikely' to result in adverse effects. The statement shown in the final report is by contrast much more limited in its scope; in making a more factual and generalised statement the

[50] Simple dissimilar action is when "the nature, mechanism and/or site of action of the chemicals in the mixture are different. Thus each chemical exerts its own individual toxic effect, and does not alter the effects of other chemicals in the mixture" (Vermeire *et al.*, 2007, p.271).

uncertainty present in the draft has been reduced, largely through the omission of any discussion of alternative types of chemical interaction. The following paragraph (1.21) had also been altered significantly in a manner that addressed Kortenkamp's comments. The final version is thus more nuanced, placing a greater emphasis on investigating the interactions at "non-toxic effect levels".

Box 3: Executive Summary of the Final WiGRAMP Report 1.20 & 1.21 – paragraphs 1.22 & 1.23 remain as they were in the draft shown in Box 2 (Committee on Toxicity, 2002b)

Implications for assessing potential health risks for humans exposed to pesticide mixtures

1.20 Studies *in vivo* with chemicals that exhibit the same target organ and the same mode of action have shown that the effects of mixtures of similarly acting toxicants show additivity (dose addition), which results from simple similar action. This is the case, over the whole dose range.

1.21 It is essential to know what happens at non-toxic effect levels, including exposure levels just below the LOAEL, in order to assess the health risk for humans exposed to mixtures of pesticides, veterinary drugs and similar substances. Generally, when exposure levels of the chemicals within a range of the NOAELs, and the components of the mixture have different modes of toxic action, no additivity and no potentiating interactions are found, indicating the applicability of the basic concept of "simple dissimilar action", which suggests that adverse reactions would be unlikely.

In responding to 1.22 of the draft executive summary Kortenkamp (2002) made a further point that it is unclear why the WiGRAMP concluded that

direct extrapolation to lower doses is invalid. Interestingly, there is no explanation for this conclusion in the final report.

Arguably, the most important paragraphs of this section of the report are 1.22 and 1.23, which have been used by the FSA to issue the following advice to consumers; advice that has been publicly questioned and disputed by scientists and NGOs alike:

> The risk to people's health from mixtures of residues is likely to be small…children and pregnant or breastfeeding women are unlikely to be more affected by the 'cocktail effect' than most other people (Food Standards Agency, 2002b)

Some of the most vocal criticism of this advice was made by environmental and health NGOs such as BRAME[51] (Harrison and Harrison, 2003) and Friends of the Earth. For example, Sandra Bell, in a statement made by Friends of the Earth (2002b) not only questioned the certainty of the WiGRAMP's conclusions but suggested that they were based on "assumptions, not actual evidence". Indeed, she goes as far to say that the WiGRAMP "uses bad science to play down risks to human health in order to justify inaction".

Kortenkamp (2002) in his written evidence also suggests that there simply is not the evidence to provide firm conclusions as to the risks posed. Notably, he again implies that the WiGRAMP's understanding of

[51] BRAME stands for the Blue Ribbon for the Awareness of ME.

the issue is flawed and overly confident in its dismissal of public concerns regarding potentially vulnerable sub-groups:

> The Working Party may deem the probability of health hazards to be low, but frankly, in the absence of evidence, we simply do not know…It is surprising to see that the Working Group dismisses possible concerns about particularly vulnerable subgroups of the population. Given the limited information available, it would seem imprudent to make such far-reaching statements. (Kortenkamp, 2002)

The criticism of the WiGRAMP was not limited to those outside of the government advisory process. Several interviewed members of the ACP were also critical, but for differing reasons. When ACP member (X) was asked about the WiGRAMP report they suggested that the WiGRAMP had been dismissive of the ACP and had overstated the potential adverse health effects of pesticides.

> "I felt that they had definitely come out saying that pesticides are really bad, and I mean my own view is that we actually don't have any evidence for that at all, one way or the other really, I felt that WiGRAMP in particular was rather dismissive of the ACP," (X) ACP Member

Thus, whereas those outside of the advisory process felt that the WiGRAMP had been too confident in using the evidence to suggest that

there were no problems, (X) felt they had been too quick to use the evidence to suggest that problems were possible.

In contrast, ACP member (N) held similar views to Kortenkamp and Friends of the Earth. In interview, (N) detailed how they gave evidence to WiGRAMP, but, like those shown above was disappointed with its findings. In particular, (N) highlights the discrepancies between the WiGRAMP's conclusions regarding the risks to children and pregnant women and those found in other regulatory guidelines, such as the European Weaning Directive and the American Food Quality Protection Act (FQPA); suggesting, similar to the argument presented in Chapter Five, that the process of pesticide risk assessment is not wholly objective but combines science, politics and expert judgement, so that decisions made by one authority may not be replicated elsewhere.

Similar to Kortenkamp, (N) suggests that the WiGRAMP report projects a certainty of knowledge about the risks posed by mixtures that (N) believes is simply not warranted given the current limitations in methodological tools:

> "Basically we know nothing, you know?…I mean the ACP does look at metabolites, but we don't have the tools to analyse a mixture of such and such, and so you say what are the options? The options are the sort of thing that they give in the Weaning Food Directive…and the FQPA in the States…so there are disparities between regulatory authorities across the world," (N) ACP Member

Despite individual members' concerns regarding the validity of the WiGRAMP's findings, the publication of the report led to a change in the assessment procedure adopted by the ACP. The Pesticide Safety Directorate (2003b, p.1) noted that as a result of the WiGRAMP report "the ACP now routinely considers the possibility of toxic interactions where two or more pesticides are co-formulated in the same product". However, while a progressive step away from the norm of assessing single substances in isolation, this additional consideration does not address the issue of mixtures where humans are exposed to more than one substance.

A key problem in changing assessment practice in line with the WiGRAMP's recommendations is highlighted by the Food Standards Agency (2005) in its "Action Plan on the Risk Assessment of Mixtures of Pesticides and Similar Substances". Here the FSA noted that new recommendations may be difficult to introduce in respect of pesticide assessment due to regulatory authority lying within EC legislation; it would be illegal for the UK to unilaterally add requirements to the authorisation process. The strict adherence by the ACP to these regulatory requirements when assessing pesticides may in part explain ACP member (X)'s frustration with the WiGRAMP report and belief that it had been dismissive of the ACP, i.e., although the WiGRAMP may disagree with the current assessment policy and in that sense criticise the ACP's approach to mixtures, the ACP is unable to formally change its approach without it being agreed within Europe, although it should be noted that it would be acceptable for the UK to raise this as an area of concern that needs to be addressed.

In summary, despite the WiGRAMP report making some progress towards acknowledging mixture specific risks within the regulatory community, its central findings were widely criticised, from one side, for failing to give due weight to the uncertainty involved, particularly in terms of potential impacts on more vulnerable populations and, from the other side, to the regulatory requirements that dictate the remit of pesticide assessments undertaken by the ACP. As such, the credibility of the resultant advice has been publicly challenged by both those within and outside government.

6.3 Pesticide residues: To peel or not to peel

This second case study discusses the advice surrounding exposure to pesticides in food. Previous chapters have discussed how pesticide residues are commonly found on and within fruit and vegetable produce. Despite implementation of regulatory guidelines in the UK relating to residue limits (Chapter Four) there remains a significant level of public concern regarding their presence in food[52]. In response to these concerns the government and others have issued advice based on a variety of evidence sources. In what follows, I will show how advice can differ depending on the evidence used and the conceptual frame in which advice is produced.

Two key players in providing 'official' pesticide risk advice in the UK are the ACP and the FSA. However, despite both being governmental bodies

[52] The 2005 Eurobarometer on risk found that 65% of the British public surveyed were worried about pesticide residues in fruit, vegetables or cereal (European Commission, 2006).

they can be viewed as having often incompatible agendas. The ACP's remit is to advise Ministers on "any matters relating to the control of pests in furthering the general purposes of Part III" of FEPA (Advisory Committee on Pesticides, 2008), whereas the FSA was established "to protect the public's health and consumer interests in relation to food" (Food Standards Agency, 2002a). These different functions have resulted in these bodies framing the role of pesticides in distinct ways. The ACP frames pesticides as a pest management tool and therefore assesses them against criteria such as utility and fitness for purpose. In contrast, the FSA frames its discussion of pesticides in the same way it does other food contaminants[53]; they are undesirable components and their presence should be minimised as far as possible.

The different framings by official bodies such as the ACP and FSA are influential in the discourses of other government institutions. For instance, in 1997, three years prior to the establishment of the FSA, the UK's Chief Medical Officer issued the following piece of advice regarding pesticide residues found in food:

> …washing fruit and vegetables before consumption is always a sensible precaution to ensure it is clean. Peeling is a matter of consumer choice, but is a sensible additional precaution when preparing fruit and vegetables for small children (Ministry of Agriculture and Fisheries and Food, 1997; Hansard, 2000).

[53] As discussed by interviewee B, a senior FSA science policy advisor.

The FSA initially based its risk advice upon the MAFF guidance. However in 2001, in light of its specific remit to provide advice to consumers, independent to that of other government departments, it requested that the ACP review the Chief Medical Officer's advice. Following discussion the ACP issued this statement:

> Washing or peeling fruit and vegetables before consumption is good hygiene. However, it is not required as a protection against pesticides residues. When deciding whether pesticides should be approved for use in the UK, the ACP makes no assumption that fruit or vegetables will be washed or peeled. (Advisory Committee on Pesticides, 2002a)

Here the ACP is clearly stating that its assessment process is thorough and that any piece of fruit or vegetable sold within the UK should be safe to eat, irrespective of whether it has been cleaned or prepared for consumption. As a result of the ACP guidance the FSA rescinded its previous advice and issued new guidance that was aligned to that provided by the ACP:

> You don't need to wash or peel fruit and vegetables because of pesticide residues. However, it's a good idea to wash fruit and vegetables before you eat them to ensure that they are clean, and to help remove germs that might be on the outside.
>
> If a vegetable or piece of fruit is especially dirty, washing might not be enough to get it clean, so then you could peel it.

> For example, carrots sometimes need scraping or peeling to remove soil. (Food Standards Agency, 2004a)

Whereas between the period of 1997 and 2002 the official advice was that washing and peeling would be advantageous in the protection of child health, the advice shown above side-steps the issue of whether it is beneficial to actively try and reduce the amount of pesticide residues consumed. Instead, it implies that where residues are present then they are at a level that is safe to eat and that the only gain in washing and peeling is one of hygiene. The fact that the FSA so quickly adopted the ACP's guidance is interesting. It suggests the FSA felt uncomfortable or unable to publicly maintain its view that as a contaminant, residues should always be reduced to the lowest possible levels regardless of whether they are deemed safe.

The interview I conducted with (G), a former member of the Pesticide Action Network (PAN), cast light on these issues. In particular, it was suggested by (G) that the FSA had no option but to back down on its previous advice, as at the time (2002) its own organisational credibility was too low to effectively challenge the ACP, an advisory body that has been established as the leading UK authority on pesticide risk assessment for several decades. This opinion is supported by Pennycook *et al.'s* (2004. p.305) assessment of the situation, which suggests that the advice of washing and peeling was withdrawn "due to internal concern that such a position would undermine the credibility of the current regulatory system for pesticides". Following this argument one can surmise that if the FSA did not alter its advice then not only would the FSA be overtly

challenging the authority and expertise of the ACP, but it would run the risk of alienating and confusing the public with mixed messages regarding the safety of pesticide treated food.

When asked about this issue, (B), a senior FSA science policy advisor, explicitly denied that the FSA was constrained by the Pesticide Safety Directorate (PSD), which was at the time part of Defra[54]. However, interviewee (B) acknowledged that the FSA's mandate and ethos of "putting the consumer first" can cause friction with Defra, which (B) stated, views its own processes and advice as robust and therefore considers the work of the FSA as an unnecessary duplication. These comments therefore suggest that despite the FSA outwardly appearing to align itself with the views and advice of the ACP, there is an underlying tension and conflict between the two bodies in relation to their remit and conception of the role of pesticides.

This is interesting on several levels. First, as shown in Chapter Four, pesticides have historically been regulated differently to substances classed as food contaminants and additives. Yet despite this regulatory differentiation the FSA appears to view them as such, at least on an internal basis. Secondly, it suggests that by classifying them as contaminants the FSA is covertly implying that wherever possible residues should be reduced as they serve no nutritional purpose, suggesting that

[54] The Pesticide Safety Directorate is responsible for the ACP. At the time of interview (2008) the PSD remained under the regulatory jurisdiction of Defra, they have since become an agency of the Health and Safety Executive (HSE).

residue reduction is preferable to non-reduction even when residues are present at levels the ACP and the EU have deemed safe. The internal organisational classification of pesticides as contaminants therefore puts the FSA in a precarious position of having to support the ACP while at the same time provide public advice as to how to minimise pesticide residues. An example of such advice is shown below. It is noteworthy that this advice directly followed the previous FSA extract, which dictated that washing and peeling was unnecessary:

> Washing, peeling fruit and removing the outer leaves of vegetables may remove residues of certain pesticides. But some pesticides are systemic, which means they are found within the fruit or vegetable. For some fruits, such as oranges, peeling will usually remove most of the residues that might be present, but small amounts of some residues may still remain in the fruit. (Food Standards Agency, 2004b)

These guidelines suggest that the FSA is ambivalent about the status of pesticide residues. According to its own institutional logic, pesticides are viewed as undesirable. However, in aligning with the ACP, the FSA is not only coerced into framing pesticides as benign but it risks undermining its public status as an 'independent' advisory body. Thus the effect of the FSA's dichotomous position is confusing advice that simultaneously denies the need to wash and peel fruit and vegetables on the basis of residues while maintaining that such action might be advisable.

Perhaps unsurprisingly, the change in FSA advice was taken as a cause for concern by a number of consumer and environmental groups such as Friends of the Earth and the Consumers' Association (Connor, 2002). In particular, Friends of the Earth (2002c) quoted the government's Pesticide Residue Committee's (PRC)[55] own report from that year to highlight that the pesticide chlorpropham had been found in unpeeled potatoes at four times the Acute Reference Dose (ARfD) for adults and 21 times the ARfD for toddlers; the same PRC report acknowledged that levels were found to be within ARfD limits when potatoes were peeled (Pesticide Residues Committee, 2002). As a result, both Friends of the Earth and the Consumers' Association argued that until it can be guaranteed that this type of produce is free from all pesticides then it would be prudent to maintain advice on methods of pesticide removal or reduction:

> Earlier this year the Government withdrew the only practical advice it gave to parents about reducing pesticide residues in food - to peel fruit and vegetables before giving it to young children. Today's results show just how ill informed that decision was. It is alarming that pesticide safety levels are still being exceeded in unpeeled potatoes and in pears - popular with young children…the Government and retailers should be acting to ensure that our food is safe to eat without having to

[55] The Pesticide Residues Committee (PRC) is responsible for national surveillance programmes and crop sampling procedures (Pesticide Residues Committee, 2009). It is not involved in the initial risk assessment of pesticides, its function is to monitor that levels found in UK produce are within the statutory guidelines.

> peel it first. But until that time the peeling advice should be brought back. (Friends of the Earth, 2002c)

Friends of the Earth continued to campaign on this issue and in 2004 published new research highlighting that the government's own data suggested there was the possibility that a number of children were potentially consuming pesticide residues at levels greater than were deemed officially safe. The following excerpt is taken from a press release following the publication:

> New research by Friends of the Earth, published in a peer-reviewed journal this weekend, shows that up to 220 young children a day could have been exposed to potentially dangerous levels of pesticides just from eating a single apple or pear…The research, conducted with two leading experts on pesticide exposure, Professor Andrew Watterson of Stirling University and Dr Vyvyan Howard of Liverpool University used mathematical modelling to measure exposure to pesticides for children aged between 18 months and four years old. Using the Government's own data on pesticide residues found on apples and pears, and information on the quantities of apples and pears eaten by young children from the National Dietary Survey, the study found that between 10 and 220 young children could be exposed pesticide residues at levels which could pose immediate and long term threats to health. (Friends of the Earth, 2004c)

In order to challenge and undermine the official advice on pesticide residues Friends of the Earth mobilised scientific credibility in three key ways. First, it noted that its research was published in a peer reviewed journal, suggesting that the quality of its research is equal to that of professional academics. Secondly, it stated that research has been conducted using recognised methods by academics that are described as "leading experts," again highlighting the degree to which its research sits within a larger scientific discourse. Lastly, the significance of the research is suggested through the fact that it has used government data, thereby minimising the possibility that it could be accused of sampling bias. Thus, Friends of the Earth aim to not only pluralise the advice available to consumers regarding pesticide residues, but suggest that its own guidance is superior to that from the government arguing that the latter fails to acknowledge the uncertainties and discrepancies in its data.

To summarise, the differences in how the Advisory Committee on Pesticides and the Food Standards Agency frame pesticides has resulted in a tension between the two bodies. The rescinding of advice to wash and peel fruit and vegetables by the FSA and its subsequent alignment with the ACP suggests that the ACP has a greater institutional authority than the FSA. The authority of the ACP throughout the history of UK pesticide regulation has been previously discussed in Chapter Four and it is interesting to observe that the FSA appears to be unwilling to challenge the ACP's advice, despite the FSA's explicit mandate to put the customer first. The dominance of the ACP can be further witnessed by the fact that the FSA did not alter its advice, despite the Pesticide Residue Committee collecting and publishing information suggesting that there are occasions

where it might be necessary to peel to ensure that residues levels remain under the ARfD. Silence on the part of the FSA on this matter therefore raises doubts as to the Agency's ability or willingness to fulfil its central consumer orientated mandate.

In this case study, I have discussed how the fragmentation of advice surrounding residues was publicly reduced across government bodies through the FSA changing its position to match the ACP's. However, in doing so it encouraged a proliferation of advice from those external to the official advisory process who have been critical of the ACP's, and in turn the FSA's, guidance. Such advice was shown to substantially differ from that of the government and can be characterised by the fact that it is more precautionary, placing greater emphasis on areas of uncertainty and discrepancies within the government's own risk assessment practices. It is therefore likely that such alternative advice will act to undermine the FSA's advice and weaken its credibility as an organisation that puts the consumer first.

6.4 The RCEP and bystander exposure

The final case study explores the 2005 Royal Commission on Environmental Pollution (RCEP) report entitled "Crop Spraying and the Health of Residents and Bystanders". The recommendations made within the report were perceived by many within the area of pesticide risk assessment as controversial[56] and the publication resulted in a series of

[56] In the consultation exercise of Defra's 2007 review of the RCEP, "Crop Spraying and the Health of Residents and Bystanders" was named as the

public exchanges between the RCEP and other interested governmental bodies, most notably the Advisory Committee on Pesticides (ACP), over what advice should be provided to farmers and the public. In the following I outline the findings and explore why the report was so critically received by the ACP.

In 2004 when the RCEP was asked to investigate crop spraying and bystander exposure the issue was not new. The RCEP itself highlights that the subject had been discussed in 1987 by the House of Commons Agricultural Select Committee and again in 1990 by the British Medical Association, which suggested that the data surrounding the effects of pesticides on human health were incomplete (British Medical Association, 1992). In 2002 the issue was again revisited at the ACP's annual open meeting and the resultant advice, produced by the ACP for Ministers, was used to frame the 2003 Defra "Consultation on the Introduction of No-Spray Buffer Zones Around Residential Properties" (Pesticide Safety Directorate, 2003a). Part of this advice is shown below:

> Members concluded that on the basis of the information currently available the risk assessment for bystanders used at present provides adequate protection, even if spray is applied to the edge of a field. The Committee has asked PSD to collect some further experimental data to provide further support to this view. Nonetheless, the Committee recognises that many may consider it socially unacceptable to spray right to the

RCEP's most controversial report, both in terms of its findings and the commissioning strategy (Defra, 2007b).

> boundary of a neighbour's property. If Ministers agree, they may wish to consider options to restrict this practice. (Advisory Committee on Pesticides, 2002b)

The above clearly establishes that in 2002 the ACP held an opinion, similar to that held regarding residues, that current risk assessment practices were adequate in protecting human health. Indeed, it suggests that a change in practice would only be valid on social and not scientific grounds. Despite continued assurances from the ACP and the Pesticide Safety Directorate (PSD) that there was no scientific case for implementing additional measures to safeguard human health, public concern remained (Pesticide Action Network, 2005b). It was in response to this concern that in June 2004 the Rt. Hon. Alun Michael[57] asked the RCEP to produce a report on the science used to assess risk from crop spraying.

The circumstances surrounding this report were unusual and breached convention; the RCEP was asked directly by the Minister to undertake the research. A key reason cited by Mr Michael for requesting that the RCEP undertook this piece of work was a desire for an "independent appraisal" of the evidence[58]; implying that bodies such as the ACP and the PSD,

[57] Alun Michael was at that time the Minister for Rural Affairs and Local Environmental Quality.

[58] The following is taken from Mr Michael's written statement: "I have listened to the concerns of campaigners who hold strong views about how crop spraying has affected their health. Their views are undoubtedly sincerely held and although no new scientific evidence was produced to support their case, I believe the time is now right for a fresh and

were comparatively perceived by the public as lacking independence. The unusual commissioning process had unfortunate repercussions for the validity of the report; the ministerial request led to a perception that the RCEP was unduly influenced in its assessment and this has since been used as justification for why the report should be dismissed. This situation has perhaps been exaggerated due to the controversial nature of the report's findings, which were at odds with the advice produced by the ACP and have since been heavily contested by other government bodies (Defra, 2007b).

In particular, the RCEP suggested within the report that there may be links between bystander exposure and chronic ill health, including multi-system and multi-symptomatic disorders such as Multiple Chemical Sensitivity (MCS) and Chronic Fatigue Syndrome (CFS). It is important to note the tentative judgement on behalf of the RCEP, as it is clear in stating in the report that on the evidence it received it would be impossible to conclusively confirm or deny such links exist. However, the RCEP propose that the risk assessment process, in particular the toxicological component and exposure modelling, is inadequate in considering the more complex health problems that have been attributed to pesticide exposure and so it is feasible that with more study links might be found to exist.

When taken as a whole, the RCEP report questioned both the current practice of agricultural spraying and the risk assessment process that

---

independent appraisal of the science." (Defra, 2004 - shown in Appendix A of the 2005 RCEP report)

underlies the conditions of use. The report made a number of recommendations, the most publicly contentious of which was the proposal for the implementation of 5m buffer zones surrounding agricultural areas where pesticide spraying would not be allowed. The negative reaction to this recommendation by other government bodies, who subsequently challenged the evidence base for this proposal, was such that this issue appears to have overshadowed other aspects of the report and has been used by these bodies to discredit the report as a whole.

On a wider note, the RCEP recommended that the regulation of pesticides needs to be restructured so that regulation is separated from the approval system. It argued that this would place greater weight than is currently available on addressing health issues associated with pesticide exposure and allow for a more active consideration of wider environmental objectives (Defra, 2007b, p.31). Such comments suggest that, like the environmental groups previously discussed, the RCEP favours a broader and more holistic approach to the assessment of pesticides than is currently in use.

In making such recommendations, the RCEP can be viewed as being implicitly critical of the ACP, its practices and its relative power within the field of UK pesticide regulation. Within the report it is explicitly suggested that the ACP regularly plays down the uncertainty present when assessing bystander exposure to pesticides through failing to adequately acknowledge alternative views and the political and ethical judgements, which the RCEP state are implicit in its advice:

> In the light of the lack of rigour in the underlying science, we have been surprised at the level of confidence expressed in advice to Ministers and the level of assurance given to the public about the safety of residents and bystanders potentially exposed to agricultural pesticides. We have concluded that the level of these assurances is not robustly founded in scientific evidence. Limitations in the data and alternative views of the science, as well as political and ethical judgements implicit in this advice, all need to be clearly acknowledged. (Royal Commission on Environmental Pollution, 2005, paragraph 6.14)

Given the strength of this statement it is perhaps unsurprising that the ACP and other governmental bodies have been extremely critical of this report.

6.41 Differences in conceptualising scientific uncertainty

The ACP's official response to the RCEP report was published in December 2005 and can be seen as the ACP trying to reaffirm its position as the UK's foremost expert advisory group on pesticide assessment. The ACP achieves this through two strategies: first, through suggesting that the RCEP exaggerated the risk and secondly, through suggesting that the RCEP was overly precautionary in its attitude towards pesticide use and management. This can be seen in the opening page of the ACP's response document:

> We consider that the RCEP's recommendation for compulsory 5 metre buffer zones alongside residential property, schools and hospitals to provide added protection against possible health risks from spray drift is a disproportionate response to scientific uncertainty…We agree that there are scientific uncertainties in these areas that warrant further research, but we think that they are minor, and no greater than the uncertainties that exist in other aspects of human health risk assessment for pesticides, or for many other environmental health hazards. (Advisory Committee on Pesticides, 2005, p. 3)

Although the ACP acknowledges that there are uncertainties, its response tries to dismiss them and reduce the perceived scale of uncertainty through a comparison with other uncertainties found within the field of environmental health. This is interesting for two reasons. First, as argued by the RCEP, until more information is gathered, the scale of the uncertainty cannot be identified due to the very fact that the data are either unknown or uncertain; secondly, it is interesting that the ACP would choose to compare bystander risk and uncertainty to other environmental risks and uncertainties outside that of pesticides, when the ACP itself is not specifically expert in those areas. This is remarkable because it dismisses the RCEP report largely because it does not consider the RCEP to have the necessary expertise with which to adequately assess the risks in this area. Throughout its response, the ACP implies that the RCEP did not fully understand the problem, was sloppy in its

assessment and reporting, and was unqualified to comment in this area. This can be seen in statements such as:

> …we draw attention to various errors of fact and logic in their report. We note that several of its most important conclusions appear to have been reached after what we consider to be an incomplete consideration of the relevant evidence. (Advisory Committee on Pesticides, 2005, p.4)

And:

> Annex 1 lists various technical errors and misleading statements in the RCEP report. Although these do not impact critically on the conclusions of the report, they are potentially confusing for the public, and suggest that the RCEP did not fully grasp the area of risk assessment on which they were invited to advise. (Advisory Committee on Pesticides, 2005, paragraph 1.4, p.5)

The ACP also raised concerns about adopting an over-precautionary attitude in relation to pesticide use and exposure. In particular, it worries that "over-precaution can send a misleading message to the public, causing them to limit their activities unnecessarily, and perhaps even generating illness that would not otherwise occur"[59] (Advisory Committee

[59] Here the ACP quote three articles that suggest prior belief and assumptions regarding the danger of pesticides and other environmental hazards can be used to predict not only when and what symptoms will

on Pesticides, 2005, paragraph 3.40, p.15). The ACP repeatedly endorse the position that precautionary actions must be consistent and proportionate to the degree of scientific uncertainty present and it strengthens its argument through suggesting that the uncertainties in this area of risk assessment are no greater than those found in "other aspects of human risk assessment for pesticides, or for many other environmental health hazards" (ibid, p3). Finally, it claims that its views are shared "by most other scientists who are involved in risk assessment of pesticides" (ibid), suggesting that the RCEP does not have the necessary expertise to make any judgements in this area and that the RCEP's advice is inconsistent with the dominant scientific discourse.

The RCEP issued a formal reply that sought to address some the ACP's criticisms. Specifically, the RCEP noted what it considered to be the crux of the disagreements, a difference in opinion over "what action it is appropriate to take in the absence of scientific certainty, where human health may be at stake", which it suggests may reflect differences in the two bodies' approach to the assessment of uncertainty (Royal Commission on Environmental Pollution, 2006, paragraph 6). In light of the ACP's comments it writes that it has as a Commission re-examined the evidence and that it stands by its recommendations, which it views as both *'appropriate'* and *'proportionate'*. To further strengthen its credibility and weaken that of the ACP, it notes that "a number of members of the ACP, dissenting from the majority ACP view, agree with us" (Royal Commission on Environmental Pollution, 2006, paragraph 7).

---

occur following exposure, but also a patient's response to treatment (Advisory Committee on Pesticides, 2005, paragraph 3.40, p.15).

A key reason given by the RCEP for why it adopts a more precautionary stance concerns the current practice within the ACP of placing emphasis on assessing the active ingredient(s) rather than assessing the mixture as a whole. In criticising the management of this area, the RCEP raise doubts - similar to those expressed in relation to the WiGRAMP report - as to the validity of the ACP's long standing position that the current assessment system adequately protects against the potential risks that may be associated with exposure to chemical mixtures. Here, it expresses concern over the possibility of synergy and that "the potential impact of exposures on the full range of the human population, has not been fully addressed, and that there remain significant areas of risk and uncertainty" (Royal Commission on Environmental Pollution, 2006, paragraphs 14 and 15); an argument that echoes that made by environmental groups in relation to residues.

This view that the RCEP acted appropriately given the presence of scientific uncertainty and incomplete or conflicting data was reiterated by (E), the former chairman, who suggested that the ACP is at times dismissive or reluctant to consider different types of evidence:

> "Well we don't say that any particular study should be believed, what we say is that the evidence is just not strong from any of them and we make a very clear statement at the beginning…what we said is that there is a lot of stuff out there which people tend to ignore, so the ACP puts aside the

> Ontario[60] study and they put aside the other things" (E) Former RCEP Chairman

(E)'s opinion of the ACP mirrors a statement made by the RCEP in relation to the ACP's assessment of risk. Here the ACP is depicted as stubborn, a body closed to alternative opinion and unwilling to carry out or endorse further research that may reduce the uncertainties described within the RCEP report, uncertainties which in several cases the ACP acknowledged:

> We accept the ACP's view that the evidence from further study might support the hypothesis that there is not a problem from pesticide exposure. That would be important. What we cannot accept is a rejection of research that seeks to reduce uncertainties in this area, particularly when this is coupled with continuing assertions that there is not a problem, and that action to reduce exposure is disproportionate. (RCEP, 2006, paragraph 20)

While the ACP had in 2002 suggested that there may be social grounds to introduce buffer zones, the RCEP endorsed the view that where there is scientific uncertainty, decisions should not be taken on the basis of science alone, but should be considered within a wider framework that includes social, ethical and economic components. The RCEP suggested that the ACP is locked into a mode of un-reflexive working which fails to

[60] The Ontario study was a systematic review by the Ontario College of Family Physicians of epidemiological literature produced between 1990 and 2003 on the health effects of pesticides (Ontario College of Family Physicians, 2004).

recognise or account for differences in perspectives regarding risk assessment and the management of uncertainty. To strengthen its argument it again makes reference to the ACP members who issued minority statements:

> But we remain concerned that the ACP seems unable or unwilling to accept that most of its advice to Ministers is based on an implicit judgement, in a context of scientific uncertainty, about the relative importance of public concerns about human health and well being. Implicit judgements are being taken on the benefits of pesticide usage and consequent conclusions drawn about what is in the public interest. The four members who disassociated themselves from parts of the ACP response were evidently also uncomfortable with this judgement. (Royal Commission on Environmental Pollution, 2006, paragraphs 24 and 25)

In addition to Defra asking the ACP to provide a response, the Department of Health asked the Committees on Toxicity (COT) and Carcinogenicity (COC) to comment on the recommendations pertaining to health (Defra, 2006a). It is interesting to note that the COT and COC appear to agree with the RCEP's conclusions in section 2.1-2.15, which suggested that no firm conclusions could be drawn regarding a causal link between resident or bystander exposure and ill health (Committee on Carcinogenicity and Committee on Toxicity, 2006, paragraph 13). However, in concluding, the COT and COC disagreed with the RCEP's recommendations [2.65] for both further urgent scientific research to

investigate a possible link between pesticide spraying and ill health and for a more precautionary approach to be taken regarding passive exposure; this was conceptualised by the COT and COC as essentially a political and not a scientific problem and hence responsibility for managing risks lies downstream with policy-makers and not scientists or advisory bodies. However, there was little recognition by these committees that the process of risk assessment and the tests performed are themselves partially subjective, being shaped by historical, social and regulatory systems.

The reviews from the COT, COC and ACP were used to formulate an official government response to the RCEP report, which was released in July 2006 (Defra, 2006b). The statement below can be viewed as an amalgamation of the responses made by the individual bodies and sets out the reasons why particular RCEP recommendations would not be enacted:

> The scientific advice received is clear that there is insufficient evidence to support the Royal Commission's recommendations for additional regulatory measures on safety grounds. Introducing regulations for other reasons such as perceived nuisance from spraying would be incompatible with the Government's Better Regulation policy. Government has therefore decided against introducing any new regulations at this time. (Defra, 2006a)

In the report the government also agrees with the RCEP's conclusions that "the evidence does not allow a firm conclusion to be drawn on causality in relation to chronic ill health" (Defra, 2006b, p.7). However, the government's response regarding how to manage these unknowns can be seen as being aligned with that of the ACP, i.e., that uncertainty is not a reason to adopt a more precautionary approach and that no additional measures can be justified on the basis of current scientific knowledge.

> The Government believes that being unable to rule out the possibility of a link can not be considered a basis to support the recommendation of an urgent need for research into any potential chronic ill health effects from pesticide exposure of resident and bystanders. Similarly there is no scientific basis for additional precaution beyond the already precautionary approach currently adopted. (Defra, 2006b, paragraph 18, p.7)

Within the press statement, Defra's Chief Scientific Adviser, Howard Dalton, did however suggest that other recommendations such as those pertaining to the development of better, more realistic exposure models would be addressed:

> We are completely reviewing the model used to assess resident and bystander exposure as part of the pesticide approvals process. The current approvals process is adequate with clear safety margins built in, however, I recognise that it

> needs to be more clearly demonstrated to the public that approvals are based on high quality underpinning science. (Defra, 2006a)

The above statement is interesting due to its contradictory message. Dalton first states that the model used in exposure assessment is to be completely reviewed thereby acknowledging the possibility that it may be flawed. However, he later denies that the current system is in anyway scientifically inadequate, despite at times appearing so to the public. This issue was touched upon in the British Crop Production Council's (BCPC) response, who similarly framed the issue as one of politics as opposed to science. In its written response, the BCPC drew parallels between bystander exposure and government advice on the MMR vaccine and the GM crops debate arguing that in all of these examples: "a balance has to be struck between the conclusions of a scientifically based assessment of risks and benefits and the perceptions by individuals and the general public of the nature of risks or sources of harm based on beliefs" (British Crop Production Council, 2006, p.2).

The BCPC, like the COT, COC and ACP focused on the challenges in obtaining evidence of causality between bystander exposure and illness, especially when illnesses such as MCS or CFS are poorly defined and without a common aetiology. It argued the net result is that such illnesses fall outside of the current hazard testing system, with the effect that it becomes impossible within the current system to determine whether particular chemicals may induce such effects (ibid). However, despite such an acknowledgement it was wary of the RCEP's call for further

research, which it suggested was likely to be “long term, expensive and not necessarily guaranteed to provide clear solutions” (ibid).

In this case study I have illustrated how the report and recommendations produced by the RCEP were dismissed by other government advisory bodies largely because they were seen to be at odds with the current assessment process and understanding of bystander risk from crop spraying. As such the advice and recommendations produced by the RCEP were not taken forward at a government level.

6.5 Summary

In this chapter I have illustrated that there are now several government advisory bodies that are involved in the assessment of pesticides, with each applying its own conceptual framework with which to assess and advise on risks. This has resulted in increasing tensions between advisory bodies and a proliferation of advice both inside and outside of government that is not always compatible. In particular, I explored how fragmentation of advice and challenges to the dominant advisory system, as embodied by the Advisory Committee on Pesticides (ACP), has been managed and what these challenges mean in respect of authority and legitimacy of advice provision.

In the first case study I explored advice surrounding exposure to mixtures of pesticides. I highlighted that despite the WiGRAMP report being a progressive step in the acknowledgement of mixtures specific risks within the regulatory community, its central findings were widely criticised for

failing to give due weight to the uncertainty involved and the regulatory requirements that dictate the remit of pesticide assessments performed by the ACP. As such the credibility of the resultant advice has been publicly challenged by both those within and outside government.

In the second case study that considered the advice surrounding consumption of residues, I illustrated that the differences in how the Advisory Committee on Pesticides and the Food Standards Agency frame pesticides has resulted in a tension between the two bodies. However, I discussed how the fragmentation of advice surrounding residues was publicly reduced across government through the FSA changing its position to match that of the ACP. One consequence of this was that this encouraged a proliferation of advice from those external to the official advisory process, which has been overtly critical of the ACP's and subsequently the FSA's guidance. This alternative advice (produced by NGOs) was shown to substantially differ to that of the government's and can be characterised by the fact that it is more precautionary, placing greater emphasis on areas of uncertainty and discrepancies within the government's own risk assessment practices. I suggested that it is likely that alternative advice will act to undermine the FSA and weaken its credibility as an organisation that purports to put the consumer first. A situation that is likely to be exacerbated by the fact that even in the face of government sourced evidence from the Pesticide Residues Committee detailing that peeling may be necessary in order to reduce residues to an acceptable level the FSA has not altered its advice.

In the third case study I discussed how the report and recommendations produced by the RCEP were largely dismissed by other government advisory bodies. I suggested that this was because they were seen to be too precautionary and at odds with the current assessment process and wider understanding of bystander risk from crop spraying. As such the advice and recommendations produced by the RCEP were sidelined by the government who favoured the views expressed by the ACP, a committee that has been shown in these case studies to consistently endorse the current assessment regime despite being repeatedly presented with evidence suggesting that there are areas, such as exposure to mixtures, that are not fully accounted for within the current assessment process.

When viewed as a whole the evidence from the three case studies suggests that while the ACP has now begun to accept the possibility of effects from exposure to mixtures through independent action or simple additivity (note only in the cases where multiple substances are combined in one product), it appears to systematically neglect the possibility of synergism, a position that has been criticised by the RCEP. Thus although the ACP has publicly rejected the criticism levied on it by the RCEP, the evidence presented here across all three case studies suggests that the RCEP was justified in making such remarks. Indeed, the evidence presented in this chapter suggests that the more reflexive approach to risk assessment as adopted by the RCEP is epistemologically superior to that of the ACP's, which appears to consistently fail to account for differences in perspectives regarding approaches to risk assessment and the management of uncertainty.

In general, the case studies suggest that there is a fundamental difference in how the ACP and other government bodies frame the risk from pesticides when compared to those actors outside of the policy process. Notably, government risk advice tends to reflect areas of greater scientific certainty, whereas advice from NGOs is typically more precautionary and tends to draw upon and reflect areas of scientific uncertainty. This would suggest that, while these framings are diametrically opposed, the two groups are unlikely to agree on how to manage any risks from pesticides.

All three case studies illustrate that it is widely recognised among advisory bodies that there are limitations in the ability to determine causal effects using the current evidence base, specifically when considering real life exposure scenarios. However, there are key questions surrounding the extent to which these limitations are acknowledged within the process of risk assessment and production of risk advice by bodies such as the ACP. Indeed, the ACP has been repeatedly criticised for using the inability to prove causation between exposure and effect to justify inaction and maintain the status quo.

In all of the case studies and in particular that pertaining to crop spraying, it is suggested that uncertainty and ignorance can be reduced through further research. However, these calls appear to have been resisted by the ACP and other government advisory bodies on the grounds that they would be resource intensive and not necessarily guaranteed to provide any further information.

Advice on pesticide residue risks therefore has to be formulated on the basis of incomplete evidence and in the knowledge that there are areas of uncertainty and ignorance. Research by Shackley and Wynne (1996) on boundary-ordering devices suggests that scientific uncertainty can challenge both science and the authority of scientists. Drawing on this it is likely that the ACP may deny the possibility of uncertainty in its assessments so as not to undermine the current regulatory system in which it is embedded.

Institutional practices are therefore shown in this chapter to not only act as frames but also as boundary objects[61] that help establish which risk questions are acceptable to ask and determine which evidence is acceptable for use in providing answers. The official regulatory framework is therefore a type of anchoring device that acts to create consensus across advisory bodies and constrain alternative interpretations (van der Sluijs *et al.*, 1998).

It was recognised within the case studies that where there are uncertainties then the selection of evidence will blend both scientific and policy considerations, therefore, any subsequent risk advice will be heavily influenced by the initial framing of the issue. Many of these points have been recognised and discussed within the STS literature. For example, Jasanoff (1991, p.29) has argued that where there is uncertainty or ambiguity in scientific knowledge used for policy then "facts alone are inadequate to compel a choice". In such situations

[61] (Star and Griesemer, 1989)

evidence selection will blend both scientific and policy considerations, with the result that policy-makers are required to seek something other than science to legitimise the choice of evidence used in risk decisions and subsequent advice. However, it should be noted that the apparent use of "sound science" in justifying decision-making does not exclude the potential for socio-political influence. Indeed, much of the literature reviewed in Chapter Two suggests that risk decisions are frequently tacitly shaped by such factors, they may just be less immediately obvious to an observer (Jasanoff, 1986; Wynne, 1992; Irwin *et al.*, 1997; Jasanoff, 1997a; Sarewitz, 2004; van Zwanenberg and Millstone, 2005); a point recognised by the RCEP in its report on risks from crop spraying which argued that tacit assumptions should be more openly discussed.

One method that has been used to gain authority and legitimacy in the area of pesticide risk assessment and advice is the leverage of 'experts' in the assessment process. However, this leverage can also lead to tensions between different expert groups as they compete to gain authority in an increasingly overcrowded arena. For example, the furore surrounding the publication of the RCEP's report on crop spraying was not simply due to differences in problem framing; in questioning the current risk assessment and management process, the RCEP was in fact questioning the authority and credibility of the ACP. This public challenge was seen by ACP member (O) as partially explaining the ACP's negative reaction to the report:

> "I think it is vested interest in one, I mean it is a defence of their expertise [ACP's], you know "this is my area and you

> know it is not for criticism", not of them specifically or of their specific discipline but of the process of risk assessment, the body of knowledge and process" (O) ACP Member

The themes of authority, expertise and legitimacy and the distinction between the right and wrong kind of expert were seen extensively in the interviews with advisory body members and will be discussed in the following chapter.

Chapter 7: Re-constructing the Legitimacy of Scientific Experts in the Post-BSE Era

7.1 Introduction

In Chapter Six I illustrated that the production of risk advice can lead to tensions not only between government bodies and NGOs, but also between different bodies within government. I suggested such tensions are not solely the result of differences in scientific understanding and conceptualisation of risk and uncertainty. They are in part a result of competing claims for authority and recognition of expertise. The institutional authority afforded to the Advisory Committee on Pesticides (ACP) within the UK has made it difficult for others, including other government departments, to credibly challenge the ACP. In this chapter I will explore the factors that underlie such difficulties; perceptions of expertise, trust and epistemic authority.

I have also shown within this thesis that the advisory system surrounding pesticides can be characterised as being in a state of flux, a system that is still responding to changes instigated by the BSE crisis of the mid-1990s and subsequent calls for the use of evidence based policy, greater transparency in the policy-making process and a widening of participation to include not only alternative sources of scientific and technical expertise but also lay representatives (Royal Commission on Environmental Pollution, 1998; House of Lords Select Committee on Science and Technology, 2000; The Strategy Unit, 2002). However, there are

significant tensions surrounding not only the role of lay people on committees but whether such people can actually be considered as lay at all (Collins and Evans, 2002). This chapter therefore seeks to answer my fourth research question: *How are competing claims for scientific expertise and for lay involvement in risk assessment being handled in the case of pesticide residues?*

The chapter is divided into four sections. In the first section I consider what it means to be the 'right' kind of expert and show that there are tensions between those experts appointed for their specialist knowledge and those appointed to ensure a breadth of expertise. I propose that it is not enough to simply be appointed as an expert in order to be perceived as legitimate. In the second section I discuss barriers to 'groupthink', highlighting that the pesticide advisory system in the UK is comprised of a tight knit community of those perceived by government as embodying specific types of expertise, who are often appointed on to committees not just because of their technical ability but also because of their shared values. However, I argue that attempts to change the membership of such committees still need to achieve legitimacy, which requires a careful navigation of the science/policy boundary to retain credibility and prevent both accusations of political interference and discord within committees.

In the third section I explore what happens when experts disagree and show that in respect of the ACP there is a desire to present assessment findings and advice as being consensually agreed and derived using the most relevant specialist expertise – thus perpetuating the myth that science speaks with one voice (Collingridge and Reeve, 1986). In the final

section I consider the effects of widening participation in advisory committees to include lay members. Drawing on the work of Collins and Evans (2002) I argue that there is a paradox; although appointed as non-experts, many lay members can be considered as possessing *interactional* and sometimes even *contributory* expertise. Paradoxically, although their expertise is frequently not recognised by those appointed as 'experts' it is their knowledge and professional competency that allows them to interact within risk discussions.

7.2 Being the 'right' kind of expert

In this section I discuss that there are competing claims for expertise from different actors. Such claims are shown to be rooted in different understandings of what counts as the right kind of expertise and who embodies this. In previous literature it has been discussed how in British advisory bodies expertise and trustworthiness is often embodied in the person. Advisory committees for example, have in the past been described as comprising the "great and the good", so that when defending recommendations it was often enough "to show that the best people were selected to evaluate the situation and to draw the appropriate conclusions" (Jasanoff, 1997a p.227). However, in the following I argue that in the area of pesticides, the situation is becoming more complicated as there are increasing tensions between the notions of experts having specialist knowledge versus experts having scientific breadth; in questions of risk it is no longer enough to simply be appointed as an expert in order to be perceived as legitimate. This tension is epitomised in how the ACP and the Royal Commission on Environmental Pollution

(RCEP) describe themselves: the ACP as an "expert committee" which values specialist knowledge[62] and the RCEP as a "committee of experts" which values scientific breadth. Both committees can be considered as being comprised of experts in the traditional sense.

Throughout the interviews, many ACP members, in particular those appointed for their toxicological knowledge, were very critical of the RCEP report on crop spraying; they frequently stressed that they did not feel that the RCEP had the *right* sort of expertise with which to make judgements in the area of pesticide risk. In particular, they repeatedly noted that with the exception of the lay members, all ACP members are experts on pesticides, with many also possessing toxicological expertise.

The issue of whether you need to be a toxicologist to be able to make an informed judgement in the area of pesticide risk was seen across the interviews and is at the heart of all the disagreements. (S), a toxicologist and member of the Committee on Toxicity (COT), suggested that toxicologists are now under pressure to protect their historically privileged position in this area: "I'm afraid toxicologists are in a rather difficult position of maintaining their own discipline". Here (S) was referring to the difficulty toxicologists face in finding a balance between communicating risk while not overselling it to enhance or maintain their own advantaged disciplinary position in risk assessment. Similarly, COT working group member (T) suggested that the pace of change in toxicological science

[62] See Irwin's (1995) Citizen Science, where extracts taken from the ACP's 1980 report on the pesticide 2,4,5-T illustrate how the ACP has been formally recognised as an "expert committee" for several decades.

meant that many of those toxicologists traditionally considered as expert and included in advisory groups can no longer be described in such terms:

> "Sometimes the science is really hard, I mean I don't understand all this genomic stuff, I will soon be out of my depth and I suspect a lot of the traditional toxicologists are, they are not experts anymore, and I just think they have got to have an understanding of the problem to be of any help," (T) COT Working Group Member

Such comments suggest that there is recognition among toxicologists that new developments and areas of interests in risk assessment are likely to reduce the need for the more traditional style toxicological expertise, and instead favour a move towards more diverse advisory membership that includes alternative specialisms.

The differences in the composition of expertise in the ACP and RCEP was reflected upon by (E), the former chairman of the RCEP. (E) saw the use of a wide range of experts in the RCEP as a strength as it encouraged a multi-disciplinary approach to understanding scientific problems, which (E) felt helped to facilitate a broader and more holistic consideration of environmental risk:

> "[the RCEP] is a body where everybody contributed to the discussion, there was no sense that because you are an economist that I can't criticise you, it was a debating

> environment…everybody knew something about what each other is doing and each person had a long track record in their area but was willing to think and argue and talk around the subject, so my view is that we bought experience and a lot of expertise, but also an ability to debate the subject in a way that you have to…you also have to make sure that the scientist is thinking about it in the context of the social environment, and that is what I think the Royal Commission does very well" (E) Former RCEP Chairman

As can be seen from the above, (E) appears not to privilege one discipline over another believing that it is important to consider the wider context of an issue through discussions between different fields. In this sense, the RCEP can be seen as valuing the type of expertise Collins and Evans (2002) describe as 'interactional'. However, it is the very fact that the RCEP study was conducted by experts from a range of disciplines that appeared to generate the most criticism from ACP members. This criticism is likely to be related to the almost diametric approach that the ACP takes in conceptualising and assessing risk and uncertainty, which may in part reflect the historical dominance of toxicologists within the Committee. Unlike the RCEP, where variety in expertise is valued, the ACP place weight on the fact that members have shared expertise and a depth of knowledge in one area, most notably pesticide toxicology.

For example, while (I), a former ACP member, suggests that in general, advisory committees benefit from having members with different expertise, they are cautious to stress that this should still be the 'right'

type of expertise; they are referring here to the fact that none of the RCEP members were toxicologists. The inference is that unless you are a toxicologist you are unable to fully understand toxicological studies or be qualified to comment:

> "Well, you want to have people with different expertise that is for sure, and you want to have people with the appropriate expertise to deal with the problems that are under investigation, and one of the problems with the Royal Commission on Environmental Pollution is that they didn't have anybody with the appropriate expertise and they didn't really recognise the limits of their own expertise and they ended up making silly scientific mistakes in the report that they produced, so you do need to have people with the right expertise" (I) Former ACP Member

Without knowing who was a member of the RCEP at the time of the report one might surmise from (I)'s statement that the RCEP was bereft of all relevant expertise. However, of the thirteen members one was a Professor of Immunopharmacology, the chair himself was Chair of Biological Sciences and Head of Cambridge University's Department of Biochemistry, another was a Professor of Plant Biology and a further three are listed as Professors in different fields of Environmental Science and Policy. The others occupied senior roles in fields ranging from chemistry to economics. This suggests that not only was there a significant degree of scientific expertise within the Committee but that several worked in disciplines directly related to toxicology.

However, the excerpt below from toxicologist and ACP member (L) suggests that (L) clearly felt that the lack of actual toxicologists within the RCEP led to it failing to understand the evidence and is therefore a reason to dismiss the report:

> "it was full of factual errors, if you look at the people involved in writing it, there is not a single card carrying toxicologist…the only toxicologist I know who happens to think it is a great report, happens to be X[63], you talk to the president of the British Toxicological Society I'm sure you would get a similar but more diplomatic answer than mine, it doesn't represent the situation and a lot of it is completely factually incorrect as well," (L) ACP Member

In the above (L) highlights the importance of being the right kind of expert if assessment findings are to be considered credible. By aligning their views with that of the British Toxicological Society, (L) seeks to reinforce the standing of their argument by suggesting their view is widespread among other recognised experts in this field, who (L) believes to be other toxicologists. This is further achieved through linking the views of the RCEP with those of toxicologist X, who (L) had previously dismissed in the interview as not having the credentials to be considered a 'real' toxicologist.

[63] X is not a reference to interviewee (X).

Similarly, ACP member (X) also suggested that the RCEP was unable to critically assess the evidence it was provided with from those claiming to have been affected by pesticides. In Collins and Evans' (2002) terms (X) is suggesting that only 'contributory' expertise is legitimate for evaluating pesticide risks and that only the specialist members of the ACP possess it. The RCEP's 'expertise' is presented as inadequate in handling such complex issues:

> "I think it is a very complex and emotional topic and I thought that, you know, they really hadn't looked at all the factors…I think you can get people who make these crusades part of the lives, it makes them so much more dramatic and interesting…with some of these people you can't be certain that they are as scrupulous as they should be, I mean are they for instance going to rush into the field that has just been sprayed and going to roll around in the stuff and say levels in my blood are terribly high, you know once they have made the point that pesticides are terrible they are going to stick with it, you would be better off with somebody like me just standing there, you know I wouldn't do anything like that, and people can take blood samples and then we would know, what the levels might be in human beings…you know I don't care what the result is I just want to know what the truth is," (X) ACP Member

Interestingly, (X)'s comments suggest that not only are there differences in expertise but also in trustworthiness. (X)'s statement suggests that

they believe that campaigners or those who have claimed to be affected by pesticide spraying are sometimes 'unscrupulous' and uninterested in the truth. They are depicted by (X) as dismissive of evidence that does not support their original position that "pesticides are terrible". Indeed, (X) suggests that many people who claim to be affected, far from being debilitated by exposure relish the attention that it can bring. In contrast, (X) and the other members of the ACP are portrayed by ACP member (X) as impartial and scientific, only interested in the truth. Yet, the ACP itself has been charged with exactly the same attributes that (X) finds so worrying in others, namely, an unwillingness to consider alternative evidence that does not support its original position on the low risk of pesticides and as defending the status quo – see Chapter Six.

In contrast, critics of the ACP questioned the ACP's depiction of the RCEP as lacking in expertise. For example, (Q), a member of the Pesticide Action Network (PAN), not only dismissed the ACP's criticism but raised the question as to whether toxicologists are in fact the best people to assess risk, especially when it is not confined to one narrow area:

> "this after all is the Royal Commission, to say that they haven't got the correct expertise is just absolute nonsense, well you might as well say well the Advisory Committee on Pesticides doesn't have the correct expertise or the Pesticide Residues Committee don't have the correct expertise, because who are they? They are toxicologists and they don't necessarily know about it," (Q) PAN Staff Member

This sentiment was echoed by (O), a non-toxicologist ACP member, who disagreed with their fellow committee members regarding their portrayal of the RCEP. (O)'s response perhaps raises the most important question in debates surrounding risk and uncertainty, namely that does too narrow a focus lead to a neglect of the wider picture:

> "I think that as a body they are, you know they are the top commission on the environment and they are appointed to be that, there is the whole issue that to make sense of what you are doing, do you really need to be an expert or actually when you are a real expert do you just see the trees and not the wood?" (O) ACP Member

In the above I have argued that there are tensions in the field of pesticide risk assessment between the notions of experts having specialist knowledge versus experts having scientific breadth, and that in questions of risk it is no longer enough to simply be appointed as an expert in order to be perceived as *'expert'*. I show that there appears to be a growing recognition among toxicologists in this field that new developments and areas of interest in risk assessment are likely to reduce the need for the more traditional toxicological expertise. Instead, it was argued that there needs to be a move towards more diverse advisory membership that includes alternative specialisms to facilitate a broader and more holistic consideration of risk. However, such a move will be difficult while bodies such as the ACP view the dominance of specialist members as a strength and more diverse memberships as problematic in solving complex risk questions. At the heart of the matter was the question over whether the

capacity to engage across disciplines (interactional expertise) was deemed to be essential or legitimate by comparison with specialist disciplinary knowledge (contributory expertise).

7.3 Barriers to solving 'groupthink'

So far I have discussed the contrast between expertise in toxicology and expertise in other areas of science as a key tension in discussions about who has the authority to comment on the subject of pesticide risk. However, toxicology is itself under pressure to change with the rise of new methods and areas of study, such as mixtures, emerging as specialisms in their own right. There are also political pressures on the ACP to move beyond its close-knit circle of members - who share similar professional backgrounds - and address the problem of 'groupthink'. However, attempts to transform this advisory system have floundered for reasons that I discuss below.

A recurring theme found in interviews was that the ACP was frequently depicted (by those external and internal to the ACP) as a committee comprised of individuals with specialised scientific training whose expert judgement was difficult to challenge either inside or outside the Committee by those possessing alternative forms of expertise and training. For example, in ACP member (H)'s account of the stepwise assessment style adopted within the Committee (H) suggests that ACP members themselves can find it difficult to challenge those outside of their own discipline. This raises the question as to whether it is not just a wider variety of expertise that may be required within the ACP and other

similar committees, but whether it is necessary to have multiple experts from the same discipline (thus acknowledging that science doesn't speak with one voice – see Collingridge and Reeve, 1986), as this may lead to a more adversarial and discursive culture where it would be harder for one member or a small number of members to dominate discussions:

> "you have a series of experts going round like that, which has its merit and its value but I have argued that why do we have to stand off like that and leave it to an individual's expertise? The trouble is if there is a toxicologist at the other end of the table and I am there to represent the environment, I am very reluctant to challenge the expert in toxicity, now I do because I have nothing to lose, but you can see that they don't want to be questioned by someone from some other discipline, they don't like it" (H) ACP Member

This perception was shared by (E), a former chairman of the RCEP who felt that the ACP does not encourage multi-disciplinary discussion and takes too much notice of one or two individuals. As a result, (E) claims that the ACP is unable to move on in its thinking. A view supported by comments made off the record by one ACP member who did not wish to be named. This member suggested that decisions can be heavily influenced by a minority of persuasive individuals who are frequently able to alter the thinking of the group by effectively communicating their own opinions; a situation that implies certain members are seen as embodying a greater degree of epistemological authority than others.

However, this perception was not limited to the ACP as members of other pesticide committees also suggested that this is a common occurrence. For example, when speaking about who has the final decision on whether an effect should be treated as adverse or not, (K), a senior toxicologist at the Pesticide Safety Directorate (PSD), stated:

> "At the moment it is EFSA, previously it was I suppose down to a majority decision, or if you like the fact that somebody could present a more persuasive case during the discussions," (K) Senior PSD Toxicologist

Despite the acknowledged limitations as shown above a common theme in interviews with advisory body members was that appointment onto government advisory committees has changed for the better by comparison with the previous approach that I described in Chapter Four. Many interviewees stressed that there are now formal procedures for appointing experts and lay persons, and that all members of government committees are required to divulge potential conflicts of interest, such as industry sponsorship or professional/financial relationships with commercial companies. This transparency in the appointment process was widely viewed among interviewees as granting committee members legitimacy in their roles as appointed experts. Indeed, many interviewees such as (B), a science policy advisor at the Food Standards Agency (FSA), highlighted the importance of expert committees being seen to be comprised of individuals working outside of government so that it can legitimately challenge policy and institutional thinking. Importantly, the appointing of those considered to be independent of both government and

industry was viewed as a significant means of safe guarding against the possibility of 'groupthink' within committees.

However, there was recognition among some interviewees (both internal and external to the advisory process) that due to the commercialisation of much academic research it is increasingly difficult to find suitable 'independent' experts, especially when, with the exception of expenses, they are not paid for their time and involvement:

> "it is becoming more and more of a problem in that there is the conflicts of interest, which they have to declare even if it is just someone in their own department who has got a grant from Bayer…also the fact that in the UK you don't really pay them for their time, so yes that can be a hindrance in getting the best people on to these committees," (K) Senior PSD Toxicologist

These limitations appear to have shaped the membership of committees such as the ACP. In effect the lack of monetary reward and time demands means that the job is likely to appeal to established academic/professional experts who have the capacity in their employment to take time out for advisory roles. In this sense, the majority of members of UK government advisory groups can be characterised by the fact that they hold senior positions and are towards the top of their professional careers. This phenomenon has been discussed by the former Commissioner for Public Appointments, Baroness Rennie Fritchie, who has

damningly described advisory committees as being full of “pale, stale males” (Press Association, 2003).

Although one might argue that there are advantages in appointing senior professionals in terms of the experience they bring, there may equally be disadvantages. For example, appointment of one type of expert, regardless of discipline is likely to impact on the nature and type of discussions held within a committee and may lead to the development of Type 3 errors, as an issue is only conceptualised within a narrow theoretical sphere. This was discussed by COT working group member (U), who was explicit in stating that the important thing in science is to ask the right questions, which in (U)’s opinion necessitates thinking about issues from a multi-disciplinary perspective:

> “until you ask the right questions you will not get the right answers and so you have got to be always asking those questions, and again I think you don’t want the same person with the same mindset, with the same wiring asking the questions all the time…I think that is the wrong direction to go in where you narrow things down, you should be going out, now I know you can’t assimilate all the knowledge that is out there but…the more you understand it the more that you will make the right choices” (U) COT Working Group Member

The inclusion of different types of experts was recognised by a small number of interviewees as important in areas such as the risk assessment of mixtures, where much academic work has been undertaken at the

fringes of more conventional toxicology programmes (these interviewees were typically those currently outside of the ACP and advisory process who were already calling for a more holistic understanding of the issue). However, recruiting those with the relevant alternative expertise was recognised by many interviewees as frequently being difficult to do in practice. This can be seen in the excerpt below taken from (K), a senior PSD toxicologist, who in discussing the membership of the WiGRAMP noted that the only toxicologist in the group who was specifically an expert in mixtures was based in the Netherlands, suggesting there are recruitment difficulties for advisory committees:

> "I suppose if you are talking about mixtures then there is a great shortage of toxicologists who really do know much about mixtures, but there was Dr Groten who has done quite a lot of work on mixtures, again I suppose it might have shown that either there weren't any mixtures experts in the UK or they didn't want to join the group," (K) Senior PSD Toxicologist

Indeed, a key feature of UK government advisory groups involved in pesticide risk assessment is that they are dominated by a small group of experts who typically share the same values and professional opinions. These academics can be better labelled as serial or professional committee members who can be characterised by the fact they have sat, sometimes concurrently, on a range of government advisory groups over the past 15 to 20 years, moving from one committee to another as soon as their appointment ends. This feature of UK advisory committees

appeared to be well recognised by interviewees, with one (J), a COT working group member, labelling these experts as ‘quangocrats’:

> “it is also true as with any quango, particularly in this country, you are stuffing them with quangocrats, or regular attendees of committees, who have got the time, are bright and talk a lot, and then you have problem of who are they representing?...There are many difficulties there relating to a quite small pool of people who are knowledgeable and competent at such things” (J) COT Working Group Member

In addition to UK commitments, many of those interviewed also sit on advisory groups within Europe and are professionally linked to each other through specialist societies. In this sense it can be considered as a tight knit community, where despite a public move towards transparency in appointments, many committee members appear to be recruited as a result of their contact with other members and an expression of shared values with the host organisation. This can be seen in the following interview extract with ACP member (L):

> (L): How did I get on the ACP? It was suggested to me that I apply to the advert,
>
> RD: Who suggested that to you?

> (L): I am not sure I should say that (laughing), several people I guess, people in the Food Standards Agency who are involved and people on the ACP as well,

Following the submission of an application form, potential members are interviewed by a panel (typically comprised of specialist non-government experts and members from government departments and agencies such as Defra or the Food Standards Agency) ostensibly to assess their technical competence in the area in which they have applied to represent. However, (L) discussed this process noting that in their opinion the panel did not have the necessary competence to assess a person's technical capability and that "it was more to assess how you would work in a committee type environment and the sort of judgements you would make". Such a statement suggests that there has been a degree of political shaping to the Committee, with interviews used to sound out potential members' decision-making thought processes and value judgements. In this sense, appointing those who publicly share an organisation's and existing committee members' values is unlikely to disrupt existing practices and may actually cement the development of groupthink; existing methods of problem framing and conceptualisations of risk are likely to remain unchallenged by new committee members.

It was this perception of new appointees maintaining the status quo and a move by Ministers to widen the expertise found within the ACP that led to

arguably one of the most contentious appointments[64] to the Committee in recent history. This incident, which is discussed below can be seen as a clear case of failed boundary work where politicians, in trying to move into the scientific terrain, actually reduced their own political and scientific credibility. Here in an attempt to increase the legitimacy of the ACP by deliberately introducing new members with alternative scientific expertise and values, Ministerial intervention had the opposite effect, reducing the legitimacy of the Committee through undermining the supposedly transparent appointments process. The following provides an account of the appointment.

In the early 2000s the ACP's recruitment strategy appears to have been altered; several members appointed after this point discussed that in addition to their 'technical' interview they were asked to undertake a second interview with Michael Meacher, the then Minister of State for the Environment. This additional interview was viewed among existing members as controversial, as it was perceived that the Minister was overstepping the boundary of their political role and illegitimately entering the scientific domain. Interview data from ACP members suggests that one appointment in particular proved incredibly divisive within the Committee; one member had been granted membership at the request of the Minister, despite them 'failing' the technical interview:

[64] To maintain anonymity appointees will not be named – the appointee in question is shown as X in the following quote, this is not interviewee (X).

> "X was not accepted technically, but the Minister said *"I don't give a damn, you are still on that committee"* and Y[65] said *"you can't do that, it is biased, it is unfair, you can't put your political will on us"* and he said *"well look, I am the Minister, I can do what I like""* (H) ACP Member

As can be seen in (H)'s extract, other Committee members were uncomfortable with this appointment. Indeed, several interviewees implied that this appointment was so contentious that a number of members had threatened to resign over it. In general, members felt that Ministerial interference undermined the Committee's credibility and threatened the legitimacy of the appointments process.

This criticism was not limited to within the Committee and the appointment was publicly condemned in a press statement by Baroness Rennie Fritchie, the then Commissioner for Public Appointments. Baroness Fritchie described the appointment as 'unprecedented', suggesting that it would "bring the appointment system into disrepute" as it undermined the work undertaken by government departments, such as Defra, to increase transparency and openness in the appointment system (Hencke, 2003; Press Association, 2003). However, Lord Whitty, the junior environment minister, who assisted Michael Meacher in the decision, stated that the appointment was "totally justified" as a means of expanding the membership to include more environmentalists within the Committee (Press Association, 2003). This suggests that the Minister at the time felt

[65] Y was an existing member of the ACP at the time of the appointment; it is not a reference to interviewee (Y).

that the ACP had too narrow a base of expert members and placed too little consideration on the wider environmental and health issues associated with pesticide use.

Indeed, (N), a dissenting member of the ACP, argued that it was precisely because of concerns surrounding the ACP's credibility that the Minister had intervened and placed this member on the Committee. In short, (N) suggests that at that time (early 2000s) the Minister had doubts over the will and ability within the current membership to reconsider current advice over the potential risks of pesticides. In particular, (N)'s response shown below indicates that they believed that the Minister felt that there was an unhelpful "yes men" culture within the ACP, whose shared understanding and conceptualisation of the risk posed by pesticides acted to maintain the status quo rather than actively challenge and question the evidence presented:

> "Michael Meacher made a decision that advisory committees should become more oppositional rather than left to the usual pairs of hands – so basically the yes men, so I think one of the reasons that happened was that after BSE where they suddenly realised that actually you know if you have got an expert committee of yes men, who are just chosen because they agree along the same lines and you keep the status quo and then when things go wrong it lands on the Minister's desk, and the best way of Ministers knowing earlier is if they have a talking shop where people argue…so I suspect as part of that process they would want to have more people from shall we

> say what I would call the more precautionary wing of environmental science on committees" (N) ACP Member

(N)'s account shown above suggests that Ministerial intervention was undertaken to create a more adversarial environment within the Committee, where existing members' views would be challenged and alternative, more precautionary based opinions would be considered. This opinion was shared by former ACP member (I), who suggested that a number of appointments had been made by Mr Meacher to encourage a more oppositional approach. As we have seen, this move was not successful.

In the above I have shown how the ACP has been variously described as a closed committee served by a small group of professional experts with shared values. The tight knit community found within UK pesticide risk advisory bodies has raised concerns surrounding the possibility of groupthink and shown how there is a perception that members with alternative expertise have found it difficult to challenge the dominant discourse and inject a more adversarial approach.

However, the evidence presented here indicates that attempts to change the membership to achieve more precautionary objectives still need to achieve legitimacy, which requires a careful navigation of the science/policy boundary, rather than a heavy-handed overstepping which can be easily represented as political interference. Additionally, as Jasanoff (1990; 1997a) has demonstrated in the US context, the adversarial approach is not guaranteed to work as members often find it

increasingly difficult to understand each other and interact productively. These ideas are explored further in the next section where I consider how the ACP has handled internal dissensions from newer members who have been successfully introduced to the Committee but who have found it difficult to be recognised as an expert.

7.4 What happens when experts disagree?

In many instances in risk assessment committees unanimous decisions are not possible as members may strongly disagree over the interpretation of evidence. In such cases, it is often necessary for those disagreeing to issue minority statements or reports outlining how their judgement differs from the rest of the group. However, some members of the ACP who have wanted to issue such statements expressed a difficulty in doing so, as in requesting this they are seen as overtly challenging other members' expert judgement.

This was discussed by (O), a member of the ACP, in relation to their views on the RCEP Crop Spraying report:

> "I have been a minority voice on that report, and it is difficult being a minority voice when you are not an expert," (O) ACP Member

(O)'s comment that it is difficult to be a minority voice when you are not considered an expert is important as it suggests the ACP has an expertise hierarchy that determines how credible a person's judgement is on a

particular subject. Indeed, the ACP has established formal rules about the remit of members in relation to their expertise stating that it considers it inappropriate for any member to authoritatively speak on behalf of the Committee on issues outside of their own discipline. This view is epitomised in the statement below taken from the minutes of the 307th ACP meeting, which suggests that it believes that the credibility of the Committee may be at risk if members are seen to overstep their position:

> The Chairman spoke to Members about dealing with the media. He reminded them that while there was no problem in their speaking to the Press, they should make it clear that they spoke personally and not on behalf of the Committee…he then pointed out that as the membership of the Committee was in the public domain, it was important that when making public statements about pesticides, members did not comment on scientific issues which lay outside their individual area of expertise. If they did this, there was a danger to the scientific credibility of the Committee. (Advisory Committee on Pesticides, 2004b, paragraph 10.1)

This statement reflects the widespread assumption that to be considered as both effective and high quality, advice issued by a collective body to government must necessarily be consensual – an assumption that perpetuates the myth that "science is one" (Collingridge and Reeve, 1986, p.11) and serves to increase the difficulty for individual members to express views that dissent from the majority. To this end on the infrequent occasions that minority statements are released by ACP

members it is interesting to note that the individual member's role on the Committee is often highlighted. Given the previous statement, such identification suggests that the ACP use this practice to suggest that dissenting members should be identified as inexpert in the matter in which they are commenting on. An example of this can be seen in how the ACP managed one member's minority statement in relation to the ACP's assessment of a pesticide literature review known as the Ontario Study.

The Ontario study was a systematic review of epidemiological literature produced between 1990 and 2003 on the health effects of pesticides by the Ontario College of Family Physicians (2004). The report indicated that there was evidence to suggest that there were in some cases links between pesticide exposure and adverse health effects, which included certain types of tumours and effects to the reproductive system. The report was formally reviewed in 2004 by the ACP, which dismissed it as: "scientifically weak, its main flaw being to draw inappropriate conclusions and make impractical recommendations for risk management on the basis of superficial consideration of an incomplete and biased selection of the relevant scientific evidence" (Advisory Committee on Pesticides, 2004a).

However, one member, Christopher Stopes - appointed as an expert in organic farming - dissented from the ACP's conclusions and issued his own response, which was published on the ACP's website. Within this minority statement Mr Stopes acknowledges that the Ontario report contained some flaws but suggests that these are not sufficient enough for the report to be entirely dismissed, as it was by other ACP members.

In his statement Mr Stopes argues that the ACP failed to adequately consider alternative views, which may hinder the formulation of future risk management strategies. Again his statement shown below suggests that the ACP is reluctant to consider evidence where there is difficulty establishing causal links between exposure and ill health:

> There may be valid criticisms to be made of the pesticides literature review of the Ontario College of Family Physicians. Some of the relevant points are outlined in the responses from the ACP. However, in my view, these are not sufficient to significantly diminish the relevance or importance of the Report, as is implied by the ACP statement; indeed I believe there is much to commend in the Report.
>
> There is a range of views on the conclusions of the Report, and I do not agree with the statement issued by the ACP. Alternative views are relevant and in my view have not been given adequate consideration. They may be very important in formulating appropriate risk management strategies to protect human health.
>
> I concur with the conclusions of the response from the Ontario College of Family Physicians to the ACP statement. “Overall we were saddened by the overwhelming negative tone of your criticisms. We can always demand better reviews and better evidence, but we should ask ourselves whether this is the best way to move policy and practice towards more sustainable

> approaches to human activity in the long-term". (Mr Stopes - Advisory Committee on Pesticides, 2004c)

To accompany Mr Stopes' statement the following written comment was posted on the ACP website by the then Chairman:

> [Mr Stopes'] differences of opinion relate to technical aspects of epidemiology and the interpretation of epidemiological data. It is important to note, therefore, that the original ACP statement was agreed by all of the members appointed to the Committee for their expertise in epidemiology, medicine and toxicology. Furthermore, it was only agreed after independent advice had been obtained from five other epidemiologists. (Advisory Committee on Pesticides, 2004c)

In the above statement the Chairman effectively reduces Mr Stopes' credibility in two ways. First, it is highlighted that the original ACP position was taken following advice from both internal and external experts, suggesting that its own judgement is one considered appropriate by other recognised experts. Secondly, Mr Stopes' credibility is further reduced through the suggestion that this disagreement is effectively in an area that Mr Stopes, as an organic farming expert, is unqualified to draw any expert conclusions on. Hence his minority statement should not be allowed to undermine the official position of the ACP as it is based on an incomplete understanding of the evidence.

This incident was commented on during an interview with former ACP member (I), who reiterated that Mr Stopes was unqualified to comment on this area. In the excerpt below (I) is referring to those members who had been appointed due to Ministerial intervention:

> "well some of them were appointed as experts but experts in, not in the areas that they were commenting on, that is for certain, so we had an expert in organic farming who was commenting on and disagreeing with the external epidemiologist about the interpretation of epidemiological evidence, well he is entitled to do that but when you report the disagreement, you have to make clear that the person who is disagreeing is not appointed as an expert in toxicology or epidemiology" (I) Former ACP Member

The practice within the ACP of encouraging members to only comment on areas related to their specialised expertise was picked up by the RCEP in its recent report on crop spraying. Here the RCEP criticised this approach suggesting that in privileging certain forms of expertise in risk discussions, other equally legitimate views, such as those held by lay members, would be excluded:

> Such an approach also calls into question the value of deliberation in scientific committees and the role of lay members, if expertise is always to be privileged in this way. (Royal Commission on Environmental Pollution, 2005, p.83)

In sum, the capacity for wider engagement with different sources and forms of expertise is diminished in this case by the adherence to the ACP norm of presenting assessment findings and advice as being consensually agreed and derived using the most relevant expertise. This perpetuates the mythical notion of science as speaking with one voice (Collingridge and Reeve, 1986). Some members within the ACP, who represent minority specialisms within the group, have therefore found it difficult to challenge the dominant discourse and publicly express their own views. Where members have issued minority statements, the ACP typically handles dissent through distancing opposing members' views from the majority by stressing the differences in expertise and claiming epistemic authority in the matter by aligning the majority view with other external experts who share the expertise of the majority.

Such privileging of expertise has been previously criticised by the Royal Commission on Environmental Pollution which has suggested that such an approach acts to reduce the value of lay input into risk discussions, an issue that I turn to in the next section.

7.5 Widening participation and lay membership

So far, I have examined the difficulties faced by attempts to widen the range of expertise in advisory committees in the case of pesticide risk assessment. In this section, I explore a second aspect of post-BSE changes in the organisation of advice, namely, the inclusion of 'lay' representatives on committees in a further attempt to widen participation.

The democratisation of advisory expertise is an area that has not only been critically examined within STS but in turn has been influenced by this growing body of academic research. For example, those such as Irwin (2006, p.300) have highlighted that even the most "science-centred government report is incomplete without a section on 'public engagement'". However, in a discussion paper exploring the move towards wider participation in risk regulation and policy, Rothstein (2003) concludes that although widening participation may increase public confidence in a regulatory regime, "broadening participation per se does not necessarily produce more democratic or robust policy outcomes than closed processes". Irwin (2006) has also suggested that there is a lack of clarity surrounding widening participation, which has resulted in a discursive struggle emerging around what counts as "legitimate talk" and how talk should be constructed within public engagement. In particular, Irwin (ibid) highlights how the twin goals of consensus building and the call for the greater involvement of 'innocent' citizens, as opposed to activists have created tensions and an often simplistic homogenised view of the public.

In the following I explore the role of lay members within pesticide advisory groups and how they are conceptualised by both themselves and other 'expert' committee members.

7.51 The role of lay members within committees

As I have previously shown in this chapter, many members of the ACP argue that the issues they consider are so technical that highly specialised

expertise is essential for making judgements that might be considered legitimate. Indeed, several stated that some issues were so technical even other experts/scientists outside the discipline in question were not qualified to comments with any authority:

> "a lot of the issues that we were considering were really quite technical and there tends to be only one or two members of the Committee who really have the expertise to pronounce with any authority on those issues, sometimes when it is down to very few people with expertise we will get external advice as well, because it is bad practice to have decisions driven entirely by one person," (I) Former ACP Member

The above statement is troubling for two reasons. First, if taken at face value then it raises clear questions over the utility of including those without expert knowledge in advisory committees, as they will be unable to fully comprehend the evidence which they are being asked to assess. Secondly, if taken as a reflection of how committee members conceptualise risk assessment, then it suggests that those without formal training or specific expertise are likely to be left out of discussions, with their views deemed illegitimate by other expert members.

By contrast, a number of stakeholders outside of the ACP advisory system, in particular those belonging to NGOs or specialisms not typically represented within the Committee, advocated the inclusion of lay members in risk discussions, as it was viewed that decisions are not wholly scientific but also incorporate values and politics. For example,

while (P), an academic mixtures toxicologist, recognised the need for the inclusion of those with technical expertise they also advocated wider participation and suggested that when decisions affect millions of people it is very arrogant of scientists to think that they alone should make the decisions. Similarly, (Y), a staff member from the Pesticide Action Network (PAN) spoke of how they were often critical of the lack of wider participation and the dominance of technocrats, when many risk decisions are in fact political in nature and so should be open to wider discussion:

> "we are very critical that a lot of those decisions are made purely by technocrats and it is often expressed in way that these issues are far too complicated for the lay person to understand, but not if it is a political decision and so we would like to have much more transparency and more appropriate participation of public interest groups" (Y) PAN Staff Member

(Y) went on to suggest that appointment of lay members can be very tokenistic as they are often excluded from the discussions because the issues are frequently presented in a way that is unintelligible to the lay-person, a tactic that (Y) joked was used to discourage participation:

> "It can be very token because if you are going to do that and you are also going to have discussions about quite technical things you really need a facilitator there who can translate some of that language so that a lay person can understand what these issues are, so if you don't have that you can either invite them and they can't follow it so they don't come again,

well may be that is actually the purpose" (Y) PAN Staff Member

The perceived necessity for high level scientific detail in advisory committees was widely discussed by advisory members who largely took the view, as is demonstrated by COT member (F) below, that it is often impossible to take a highly technical subject and present it at a level that can be understood by the general public:

"you can't take a highly technical subject [Toxicology] and make it all completely understandable by I think they say a level suitable for a twelve year old, that would be inappropriate because you couldn't communicate some of the technicalities" (F) COT Working Group Member

However others outside of the advisory process, such as academic toxicologist (P), suggested that if the public or the lay committee members do not understand then the scientists or experts are not doing their job properly.

Those sitting within advisory committees typically regarded the presence of lay members in three non-exclusive ways: first, that their presence was an irritant as it dumbed down discussion and suggested that they as experts could not be trusted; secondly, that they were helpful in assisting the experts consider issues from a consumer perspective; thirdly, that they were welcome as it highlighted to a wider audience the hard work and effort that is inputted by expert members. In all categories lay

members, although appointed members of the committees, were presented as being outside the actual decision making process, which was viewed as the preserve of experts. Examples of these types of categorisations are shown below.

Several interviewees made reference to the fact that the presence of lay members acted to reduce the number of experts present and that lay members often did not understand what was being discussed within a committee. As such discussions often had to be held at a simpler level than they otherwise would be to ensure that all members understood the debate. However, although this proved to be an irritant for some, others could see that it sometimes prompted the experts to be more articulate and exact in what they were saying. For example, the excerpt from COT working group member (J) below is indicative of what other advisory body members discussed in relation to the role of lay members:

> "It has undoubtedly had drawbacks as it has reduced the number of technical experts on the Committee in order to maintain the numbers, it can lower the level of discussion to an extent because you have to explain things far more clearly, that can be an advantage as people have to be far more certain in making their statements or claims at a technical level, it should increase public confidence, I don't think it has but I think that is a failure in how advice is presented…it is also a problem of the self-selection, the people who have applied to go on to these committees by and large are those

not just with a genuine interest but those who have an axe to grind," (J) COT Working Group Member

The latter part of the (J)'s comments reflected a common perception among advisory group members, that the lay people who were appointed often applied to join because they had some sort of mission that they wanted to accomplish whilst on the committee. In this sense, many members, such as ACP member (X), described how although they saw no need for lay members, their presence was tolerated as long as these members were 'sensible' and apolitical. Here, as in (J)'s comment shown previously, the presence of lay members was seen by (X) as a method used by government to raise public confidence in advisory body decision-making. Interestingly, (X)'s comments also reflect the previous discussion shown in 7.3 where it was highlighted that members often have large demands made on their time with little financial reward. Indeed, many interviewees, such as (X) presented their committee roles in an altruistic light, feeling that it was their duty as experts to give something back and make full use of their professional knowledge:

"I think it is fine provided that you have sensible lay members who don't have an axe to grind, I mean provided that they can see that we are doing the best we can with the information , but it is a modern trend and I am sure we would function just the same if we didn't have lay members, I think you have to respect professional integrity, I mean we aren't doing it for the money because the money is pathetic, you know it is a huge amount of time so people are only there because they feel

> they ought to be there, so I actually think it makes no difference but I think it does from the external perception" (X) ACP Member

Similar to (X), COT member (T) spoke of how they had experienced lay members getting in the way of discussions, sidetracking members through raising issues that were in their opinion simply not relevant. Like ACP member (X), (T) draws characterisations of the lay members, labelling the 'good' ones as those who keep quiet during the scientific discussions in which they are perceived by other members to have no expertise in:

> "sometimes the lay person doesn't understand the issue and if that happens then those people don't tend to stay on the committee very long, and they don't even represent the general public very well because it is almost as if they haven't really understood what the committee is trying to do, where as the good ones or the helpful ones keep quiet during the scientific discussions but when it comes to the decisions, when it comes to expressing it, making sure it is forceful enough or simple enough then they are very helpful, and picking up on social aspects which perhaps the scientists have not really thought of," (T) COT Working Group Member

However, (T)'s final point indicates the areas in which lay members were widely considered to be useful by their expert counterparts, namely, raising social or consumer aspects and helping the experts communicate

more effectively. This latter point was very prevalent throughout interviews with advisory body members. Lay members were typically viewed by other members as being there to flag up those areas that required additional explanation, as (F), a member of COT stated:

> "[having lay members] has been very useful in understanding how to communicate and how much detail and transparency is required, so we think we are being transparent but in actual fact we are being very technical and so it is not transparent to anybody, well except another expert, but some of them will say in no uncertain terms *"this is just gobbledy gook to us, you have to re-write it so people can understand it",* and that has been very helpful" (F) COT Working Group Member

However, (F) went further and stated that the usefulness of lay members was also in the fact that they could feedback their experience to the public and highlight how seriously the expert members took their role and how hard committee members work to ensure the right decisions are made. Again the lay members are presented as being external to the actual decision-making process:

> "I think lay members have generally come to appreciate the extent to which the committees deliberate the issues and how seriously they treat it and how thoroughly they go through the data, which maybe, well I don't know what they thought but some of them have said to me afterwards we are really surprised at what lengths you guys are going to, to reach a

> conclusion on this, so I think that has been beneficial," (F) COT Working Group Member

However, how far lay members can really report back to wider publics is, when considering the evidence I collected, debatable. For example, many committee discussions, such as those held during ACP meetings, although minuted, are closed to the public due to commercial sensitivity. Other meetings such as those held by the WiGRAMP were organised according to Chatham House rules, indicating that no member should directly divulge what was discussed during a meeting. It is therefore unclear in what capacity lay members can actively talk about their role. This is especially true for lay members present in committees such as the ACP, where as previously discussed all members are actively discouraged from publicly speaking on behalf of the Committee in areas outside of their expertise. One ACP member (O) discussed this, detailing that they saw their role as a lay member as being to comment on the process of decision-making rather than the decisions themselves, i.e., as a *procedural* expert:

> "Well it is being a sort of go between if you like, between the experts and the public, and you are supposed to represent the lay view and or communicate to the public, but there is a middle way, which is in other words being like an observer, because I might not know all the expertise that goes on, but I can comment on the process" (O) ACP Member

7.52 The paradox of the expert lay member

As I have noted throughout the thesis many lay members are not simply just members of the public but are staff of NGOs or other interested consumer groups. In this sense the boundaries of their roles are often blurred as they are expected to act as lay members when in fact they may possess considerable expertise or authority in a particular area. In this sense, if we were to apply Collins and Evans' (2002) classification, many lay members can be considered as possessing *interactional* expertise and those have been trained and previously practiced as scientists could even be described as possessing *contributory* expertise; both characterisations call into question the legitimacy of appointing them as 'lay'. Indeed, their expertise and authority is often the reason why they have been asked to join a committee in the first place.

This recognition that lay members are often not lay in the strictest sense has been widely discussed by others such as Eden (2005) and Yearley (1992 -b) – see Chapter Two - whose research on NGOs indicates that far from being just consumers of science many NGO staff produce, consume and publish scientific research. These conclusions are supported by this research. For example, many of those that I spoke with working within NGOs discussed how they and their colleagues had science training and practical work experience. However, although staffs were often trained as scientists they typically did not carry out primary or field research. Instead, they saw their role as synthesisers of other's research with the intention of drawing conclusions and providing "independent information on pesticides for governments and decision makers, researchers, media,

concerned citizens and other interested groups" (Pesticide Action Network, 2005a).

The fact that many lay members interviewed had scientific training was seen as an advantage by them, with several suggesting that it gave them or their organisation credibility within the pesticide community. For example, (Y) from the Pesticide Action Network, spoke of how they believed PAN's credibility was based on both the quality of their information and the expertise of their staff:

> "I think in more general terms our credibility is really based on the information that we have and the fact that we are not screaming lunatics, we are not radicals saying you have to stop using pesticides tomorrow and that we realise that there is a long way to go, and that the quality of us is in our information and the people that work here and their expertise and background, this all adds to our credibility" (Y) PAN Staff Member

However, despite many NGO staff members, and in particular those that are chosen to become members of advisory groups, possessing such skills they are often not recognised as having expertise by other committee members or those assembling the committees. This suggests that there is some confusion as to their role; they are not considered to be experts yet at the same time cannot be strictly categorised as lay as they possess sometimes considerable subject knowledge, certainly far more than an average or disinterested member of the public. PAN staff member (Y)

spoke of this paradox, detailing how although members of PAN were often asked to join pesticide advisory committees because of their subject knowledge, they were asked not as experts but as public representatives. This suggests that not only are NGOs and interested consumer groups conceptualised by government as representing the views of the general public, but that real 'layness' - a complete lack of training or knowledge of the area - is not valued within government advisory committees in this field.

This suggestion can be seen in an extract from (K), a senior toxicologist at the Pesticide Safety Directorate (PSD), who spoke of how Peter Beaumont, a previous PAN staff member, had joined the WiGRAMP group as a lay member as opposed to an expert from a pressure group:

> "I think WiGRAMP had a good range of backgrounds and yes you had classical toxicologists but you had statisticians, Peter Beaumont was there not necessarily as a pressure group but as a lay member," (K) Senior PSD Toxicologist

The use of expert lay members was also discussed by lay ACP member (O), who noted that the ambiguity in their role could lead to confusion during committee discussions as it was unclear in which areas of discussion they should be involving themselves in:

> "I do have a specific problem in that having been appointed as a lay person I am actually a bit of an expert, right? So I am little bit uncertain of my ground, cause I am not lay but I am

> called a lay member, but when as I was actually recruited as a lay member, they wanted somebody who was going to understand what was going on" (O) ACP Member

Interestingly, not only do (O)'s comments suggest that like those appointed for their expertise, lay appointments are also politically shaped and involve the matching of individuals' social values to those of the Committee, they also provide an explanation as to why certain types of lay members are more likely to recruited. This explanation appears to be linked to comments previously discussed regarding other committee members' perceptions of lay members; that they are frequently seen as having an axe to grind or that their presence is an irritant as they do not understand the issues being discussed. (O)'s comments therefore suggest that particular types of lay people are recruited precisely because they are not lay and so can therefore, at least in principle, actively participate in the 'expert' discussions. Indeed, this research suggests that within the pesticide risk advisory area, lay members, like the experts, are often drawn from a small pool of people who can be more accurately described as "professional lay people", who as several interviewees noted move from one committee to another. For example, PAN staff member (Q) discussed how they are invited to sit on a variety of committees because of their knowledge of the area:

> "we sit on quite a lot of them, so we go to the pesticide forum, the voluntary initiative steering group and various other groups such as the PRC…we are invited on because we are recognised as the knowledgeable expert in the area of

> pesticides, so we are invited to sit on these things and be encouraged, often to be the sort of contrary voice if you like" (Q) PAN Staff Member

It was this type of lay member that was typically seen among interviewed 'expert' members as being the most useful type of lay person as they were considered as being able to understanding the science:

> "that is why I say that there are these professional ones who get used to the other scientists and they may have a scientific background themselves or they know about the science a bit, so some lay people are more use than others," (T) COT Working Group Member

Another reason given by 'expert' members as to why these types of expert lay members were most useful was that the process of being on a committee was widely viewed as a learnt skill. For example, (J), a member of the Committee on Toxicity (COT), wished that "we had some means of teaching people how to be a member of a technical advisory committee". Likewise, (T), a member of the COT described how the lay members who they felt made the most impact within the Committee were those who understood the process, which (T) argued could take several years:

> "I mean there is this familiarisation process, you really need a term or three years or something before you get used to a committee, and maybe they are so familiar with it that they

know what to say that will make an impact, and so they are influencing change," (T) COT Working Group Member

To summarise, I have shown that there are tensions in the appointment and use of lay members within pesticide advisory committees. While they are often publicly appointed to act as the *innocent* public (Irwin, 2006) they can frequently be characterised as possessing *interactional* and sometimes even *contributory* expertise (Collins and Evans, 2002). Indeed, they often appear to be selected specifically because of these attributes.

7.6 Summary

In describing the symbiotic relationship between science and politics Mukerji (1989) has highlighted how government officials are able to legitimise their decision-making through presenting them as being based on expertise. In the UK, since the 1960s expert advisory committees have been used to supply the specialist expertise that was seen as lacking within the civil service, who due to resourcing issues could only be viewed as embodying more generalist skills – see Chapter Four for further detail.

However, as I have shown throughout this thesis the area of pesticide risk assessment and management is complex and tensions remain between those experts who value specialist knowledge and those who place value on the capacity to engage across different sources of knowledge in risk assessment. In the words of Jasanoff (1997a), it is therefore not enough for the government to simply appoint "the great and the good" in order to

create legitimacy in risk decision-making. Coupled with the traditional reliance on specialist scientific expertise I have discussed that there has been a move towards wider inclusion and the use of lay members, which was shown to create tension within committees due to differences in how their role is understood and how their knowledge is conceptualised by other members.

At the beginning of this chapter I argued that despite a move towards wider engagement and recognition among some advisors that new developments in pesticide risk assessment are likely to reduce the need for the more traditional toxicological expertise, the right type of expertise has remained narrowly defined within the Advisory Committee on Pesticides (ACP). In particular, I illustrated using interview data that the majority of those working within the ACP believed that certain types of formal expertise were necessary to understand and effectively assess the often complex information found within the pesticide risk literature. The expertise that appeared to be most highly valued among this group was shown to be toxicological; a finding that suggests the historic privileging of toxicologists in the pesticide regulatory community persists with the effect that other forms of expertise are either excluded from or play only a minor role in the ACP's discussions.

The emphasis the ACP place on a focussed contributory style expertise, as embodied in toxicologists, can be seen as a direct contrast to the nature of expertise in the Royal Commission on Environmental Pollution (RCEP) – a body I have previously shown the ACP to be critical of. The RCEP argues that to truly understand and manage risk there needs to be a move

towards more diverse advisory membership that includes alternative specialisms to facilitate a broader and more holistic consideration of a topic. In this sense the structure and framework of the RCEP encourages a more conscious discursive expert, one who is aware of the wider picture and willing to talk around a subject. However, the evidence presented within this chapter suggests that such a move will be difficult while bodies such as the ACP view the use of very specialist members as a strength and more diverse membership as problematic in solving complex risk questions. At the heart of the matter is the question of whether to be effective you require contributory or interactional expertise or a hybrid of both? This question has been previously discussed within the STS literature with Jasanoff arguing that: “The most valued expert is one who not only transcends disciplinary boundaries and synthesises knowledge from several fields but also understands the limits of regulatory science and the policy issues confronting the agency” (Jasanoff, 1990, p.243).

Such a statement would on the face of it appear to favour the model proposed by the RCEP. However, while the ACP have been externally criticised by the RCEP, NGOs and some Ministers for their narrow focus and unwillingness to consider the new, the RCEP have been criticised by the ACP and other government departments for failing to fully recognise the policy issues surrounding pesticide risk and for presenting impractical advice that was widely considered to be not only undesirable but also unachievable within the current regulatory framework. There are therefore difficulties in extending Jasanoff’s model of the ideal form of advisory expertise in practice.

To understand the attempts to transform the ACP, the appointment system was examined and it was found that advisory bodies such as the ACP are populated by a small number of professional experts or 'quangocrats'. In particular, despite a supposedly transparent appointment framework there remains a perception by some government staffs, NGOs and even a minority of ACP members that groups such as the ACP are dominated by a small group of scientists, who share a similar value system and whose judgements can be difficult to challenge by those who are not considered to have the appropriate expertise. I suggested that this situation may be linked to a desire within the ACP to present assessment findings and advice as being consensually agreed and derived using the most relevant specialist expertise. In an attempt to diversify the ACP membership and address the perceived issue of groupthink, Ministerial intervention had been used; however, this was shown to be problematic as it raised questions surrounding the legitimacy of the appointment process

Post-BSE there has been a public move within government to ensure that decisions surrounding risk and advice are not only transparent but include the input of non-experts or lay people. However, using the evidence presented I argued that there are tensions surrounding not only the role of lay people on committees but whether such people can actually be considered as lay at all. Those sitting within pesticide advisory committees were shown to typically regard the presence of lay members in three non-exclusive ways: first, that their presence was an irritant as it dumbed down discussion and suggested that they as experts could not be trusted; secondly, that they were helpful in assisting the experts consider

issues from a consumer perspective; thirdly, that they were welcome as it highlighted to a wider audience the hard work of the expert members. In all categories lay members, although appointed members were presented as being outside of the decision-making process, which was viewed as the preserve as experts.

A key concern that was raised by 'expert' committee members regarding the presence of lay members was that they are not equipped to understand the often highly technical debates; as such their appointment was frequently perceived by both expert and lay members to be tokenistic and often resented by those appointed for their technical expertise. Indeed, there was a suggestion made by some ACP committee members that some issues discussed in meetings were so technical that even scientists with expertise in alternative academic disciplines were not qualified to comment with any authority. This raises the question of whether advisory committees not only need to consider diversity between subject areas but also within, e.g., through the recruitment of multiple members from the same discipline to encourage a more adversarial and democratic discussion of the issues and risk assessment literature.

Hoffman (2003), has argued that experts will often use technical jargon, which acts not only to exclude the lay community in discussions of risk but also as a form of epistemic hegemony that devalues certain forms of knowledge (Adorno *et al.*, 1976). However, research undertaken by Wynne (1982; 1996) indicates that lay knowledge is often of critical importance in situations of scientific uncertainty; filling existing knowledge gaps and raising questions overlooked by experts. The

research that I have presented indicates that lay members in this area were most valued by other committee members not for their ability to fill knowledge gaps but for their ability to provide a consumer perspective that may be lost in very technical debates.

However, the findings I present suggest that there is often a paradox in the appointment of lay members, as although appointed as lay they often possess considerable expertise. Indeed, they often appear to be selected specifically because of these attributes, as there is recognition that membership of advisory committees requires certain skills that would be absent in the 'innocent' citizen (Irwin, 2006). Certainly, the lay members of the pesticide committees that were interviewed as part of this research were not lay in the sense of Wynne's (1996) sheep farmers. They often possessed relevant formal qualifications and training and in other situations they would be described as expert – although they often were not recognised as such within the committee structure. The labelling of lay thus seemed to be applied to either distinguish their expertise as separate to the rest of the group, i.e., to highlight they were not for example a practising toxicologist, or to reduce their ability to impact on discussions.

Many of those that were included as lay members were often employees of NGOs working in pesticide related fields. Previously, it has been argued that while NGOs can be identified as organisationally different from 'unorganised' citizens (Breckenridge, 1999), they are included in policy-making exercises not because they possess expertise, but because they represent a particular value system that is shared by their members. In

this sense, they are not viewed as experts but as representatives of public groups or movements. This view was seen in this research where it was found that many NGO members, despite having scientific qualifications and subject expertise, were asked to join committees to represent the view of the wider non-expert public. Additionally, there was a perception among members interviewed that they should feedback their role to the public. However, I questioned to what extent this is possible given the strict codes of conduct that members must adhere to in respect of confidentiality. It would therefore be easy as Irwin (2006, p.316) has previously suggested to conclude that "there is little evidence that public talk has brought about a wider cultural and institutional transformation". However, the evidence presented here suggests that such a conclusion does not reflect the nuance of the situation; although wider participation in the field of pesticide risk assessment appears from this analysis to be limited in scope, it can still be described as a progression from previous models. However, until alternative forms of expertise are recognised as legitimate this research suggests that it will remain difficult for those outside of the dominant expert group to make any real impact in committees such as the ACP.

Chapter 8: Conclusion

8.1 Introduction

In this thesis I have examined how the scientific advisory system in England and Wales has responded to concerns about the risks of pesticide residues in food and demands for wider engagement in the formulation of advice. Specifically, I have explored how the Advisory Committee on Pesticides (ACP) frames and manages scientific uncertainties in risk assessment, and why some bodies outside and within government are critical of the ACP's approach that is centred in the conventional single-chemical, high-dose-response paradigm of toxicology. Although some of these challenges date back to the early history of pesticide regulation in England and Wales, the emergence of scientific research employing newer methods to assess the effects of chemical mixtures and chronic low-level exposure has stimulated new concerns about the risks posed by pesticide residues for human health.

In attempting to explain how the ACP is able to bracket the majority of these challenges, I have drawn on literature from the field of Science and Technology Studies (STS) to make three key arguments. First, it is perceived by the ACP and some other government advisory bodies that change is unnecessary since established methods of pesticide risk assessment represent an exemplar for other domains. Secondly, the selection of evidence by the ACP and other related committees such as the Committee on Toxicity (COT), is profoundly shaped by prior regulatory guidelines that in providing standardisation and quality

assurance act to frame advisory judgements and constrain the selection of risk assessment studies that are considered as admissible. Thirdly, fundamentally different notions are at play in terms of what constitutes legitimate expertise and who should embody it.

All three arguments have implications for the two major trends which provided the background to my research, i.e., post-BSE attempts to make the role of scientific advice in British policy-making more transparent, participatory and 'evidence-based' and, the attempt to introduce new paradigms of chemical risk assessment in the advisory process. I shall explore these themes further in this concluding chapter.

In section 8.2, I summarise the analysis and main findings presented in each of the previous chapters and highlight some of the difficulties encountered in conducting this research. In sections 8.3 and 8.4, I explore the policy implications of this research and possible areas for further inquiry.

8.2 Summary of findings

In this section I will review and summarise the key arguments made in each chapter and consider how this research has addressed the overall aim of understanding: *How are the twin challenges posed by changes in the organisation of the British advisory system and by emerging scientific uncertainties in the chemical risk assessment managed in the case of risk assessment of pesticide residues, and to what effect?*

In the introductory chapter I set out why I had chosen pesticide residues as a case study, highlighting the complexity found in pesticide risk assessment and regulation. Specifically, I discussed how although the process of assessing risk from single chemical substances is considered by those working in the field to be well established and robust, other chemical related risks such as those created from exposure to chemical mixtures are increasingly recognised within the scientific and policy literature as being less well understood; often being characterised by a high degree of uncertainty (van Zorge, 1996; Weinhold, 2003; Wharfe *et al.*, 2004). Indeed, I illustrated that previous assumptions, made by both scientists and regulators, suggesting that exposure to low-levels of chemical mixtures are unproblematic to human health are being challenged by NGOs and some scientists, with newer research that often utilises novel or non-validated toxicological methods now beginning to suggest that interactions at low-levels may cause toxicological effects (Colborn *et al.*, 1993; Henschler *et al.*, 1996; Rajapakse *et al.*, 2002; Royal Commission on Environmental Pollution, 2003; Sheehan, 2006; Christiansen *et al.*, 2009). A key area of concern among NGOs and some scientists regarding low-level exposure to chemical mixtures was shown to be the consumption of food containing pesticide residues.

Despite a growing body of literature suggesting that exposure to mixtures of low-levels may be problematic the consumption of multiple residues and the potential for interaction remain largely unaddressed by the standard single substance assessment approach favoured by the UK's pesticide assessment committee, the Advisory Committee on Pesticides (ACP). This has led many groups including scientists, campaigners, policy-

makers and advisory bodies to call for greater use of integrated approaches that consider realistic multi-chemical, multi-route exposure scenarios (IPCS, 2001; Pesticide Action Network, 2002; Friends of the Earth, 2004b).

As in other scientific advisory areas, I illustrated that the advisory system surrounding pesticides can be characterised as being in a state of flux; a system that is still responding to changes instigated in the mid-nineties by the most prominent of all UK food safety crises - bovine spongiform encephalopathy (BSE) and the risk of its transmission to humans. The controversy surrounding the transmission of BSE to humans was described as a catalyst for change in the organisation of scientific advice in general and in the case of food-borne risk in particular. Notably, I detailed that Whitehall introduced guidelines for greater transparency in the scientific advisory process and a widening of participation to include not only alternative sources of scientific and technical expertise but also lay representatives. Government departments were also given guidelines to follow the tenets of 'evidence-based policy'.

In Chapter Two, I set out my reasoning for grounding this research in the field of STS and literature from this discipline was explored to consider the relationships between science, expertise and decision-making. A key feature of the pesticide residue debate – as shown throughout this thesis - is that policy decisions surrounding the level of acceptable risk are frequently made under conditions of scientific uncertainty with the result that the scientific basis of decisions are regularly challenged by dissenting actor groups outside of the immediate policy-making process. Uncertainty

in the risk assessment process also suggests that policy decisions can never be wholly scientific; instead, they are likely to interlink science, expert judgement and political values, factors that may not always be explicit when safety standards are set, an issue that I highlight has been previously widely discussed within the STS literature - see Irwin *et al.*, 1997; Levidow, 2003; Guston, 2004; Sarewitz *et al.*, 2004. On this basis, I described the assessment of risk from exposure to pesticide residues as an area of "regulatory science" (Weinberg, 1972; Ashford *et al.*, 1983; Jasanoff, 1990; Harris *et al.*, 2001); where *regulatory science* is used to describe the blurred area between science and policy, where questions may be asked of science but cannot be fully answered through its application.

Science and values were shown in this review of literature to be inherently linked; from the initial framing of a problem through to choice of methodology to finally finding and agreeing upon a solution. The reliance on "sound science" in risk assessment and advice, and the presence of scientific uncertainty was shown through the use of previous case studies and research literature to be a cause of inaction and a tool that can be manipulated within policy-making, suggesting that uncertainty itself is complex, and needs to be understood in its social context. I further discussed that while the principles found within the domain of regulatory science can be used to mediate scientific uncertainty and so prevent inaction, they raise questions that range from issues of validation to the involvement of value judgements in public policy.

The themes discussed within this chapter were expanded upon within the empirical study detailed in the proceeding chapters.

8.21 Research methods

The third chapter discussed the methodological approach adopted within this research - a combination of documentary analysis and semi-structured interviews. In this section, I explore some of the difficulties that limited some of the early aspirations for data collection.

The aim of documentary analysis was to achieve a contextual understanding of the debates surrounding exposure to pesticide residues, this in turn helped shape the design of my research and inform my interview based fieldwork. In particular, I was interested in reviewing not only STS, sociological and scientific studies but also the advisory literature produced by the Pesticide Safety Directorate (PSD), the Advisory Committee on Pesticides (ACP), the Royal Commission on Environmental Pollution (RCEP) and the two working groups of the Food Standard Agency's (FSA) Committee on Toxicity (COT): WiGRAMP and the VUT[66]. Literature from NGO groups such as the Pesticide Action Network (PAN), Friends of the Earth and the Soil Association (SA) was also reviewed.

[66] Working Group On Risk Assessment Of Mixtures Of Pesticides (WiGRAMP) and the Working Group on Variability and Uncertainty in Toxicology (VUT).

In general, the move towards transparency within government departments meant that much of the documentary evidence, such as advisory reports and associated documents, was readily accessible online. Additionally, recent changes regarding the access of historical archived data also meant that the research required to explore my first research question relating to historical risk assessment and regulatory practices – discussed in Chapter Four – was easily obtainable from the National Archives. However, there were a number of instances where information proved difficult to access and resulted in changes to my original research plan. One example of this - discussed in Chapter Three - regarded access to the draft WiGRAMP report. In this case I was unable to obtain the whole draft report and the documents relating to the consultation as I had hoped at the start of my research. I was therefore compelled to contact those who commented on the draft to build up a picture of how it may have changed between draft and publication. Other documentary evidence that proved less useful than initially expected were documents detailing internal advisory committee events, such as the minutes for the ACP and the RCEP meetings; although published online these documents generally contained only high level outcomes. As such it was difficult to determine the actual discussions and negotiations that took place within these meetings that led to the production of these outcomes.

Interviews were conducted during 2007 and 2008. A semi-structured approach was chosen to allow participants to explore themes and issues that they felt to be important. Since I was interested in understanding how scientific literature (including recent work on low-level exposure and mixtures) is assessed in the course of producing risk advice, I

concentrated on interviewing members of three UK advisory bodies that have recently debated such issues: the ACP, the COT and the FSA. In total 25 interviews were conducted: 16 interviews with those associated with government advisory committees (members of the PSD, ACP, COT, RCEP, FSA), four with members of NGO groups (PAN and the SA), two with representatives from the agrochemical industry and three with mixtures toxicologists, who worked in academic research. Although useful in providing context to this research, much of the data collected from the interviews with the mixtures toxicologists were not relevant to the main focus of this thesis regarding how those within the advisory process were treating this type of research.

While the majority of those I had planned to interview were not only easily contactable but also willing to participate, there were others who were more difficult to access. In general it was those working in academia or government that proved the easiest to contact. There were a small number of advisory group members (less than 5) that I had initially wished to speak with but could not, however, this was due to logistical issues as opposed to reluctance on their part to participate. On such occasions I substituted these interviewees with others working in the same area, some of whom had been recommended by the person initially contacted.

The group of people that proved most difficult to contact and interview were those working within NGOs and industry. These difficulties were expanded upon in Chapter Three and included reasons such as lack of staff resources, changes in research direction and trade secrecy. I

therefore had to re-evaluate my methodology and complement those interviews I could conduct with written data, such as formal publications and data from official websites. In this sense I had to triangulate smaller pieces of data to gain an understanding of the whole.

Constraints both in terms of time and resources always affect how research is conducted and this thesis is no different. Due to such constraints I chose to focus on interviewing those working within advisory bodies. Although more interviews with those working in the field of mixtures toxicology would have been useful, very few of these toxicologists work within the UK and such exploration would have required international travel. Additionally, it was only once I had begun to analyse the data that I saw how frequently references to the RCEP occurred among members of the ACP. These interviews had been spread out over the course of a year and this connection was therefore not immediately apparent. I would in hindsight have liked to have conducted further interviews with those involved in writing the RCEP's report on bystander exposure. However, this was not practical. Also, much of the information important to this thesis was actually contained within the report and its associated documents.

8.22 History of pesticide regulation in England and Wales

In Chapter Four, using documentary evidence, I explored the first research question: *How have the potential risks of pesticides been*

historically assessed and regulated in England and Wales since their first commercial use in the mid-twentieth century?

In order to contextualise current pesticide assessment and management it was necessary to consider how they have traditionally been managed. Historical analysis reveals that the decisions made during the 1950s and 1960s strongly shaped the role and remit of government advisory bodies and current assessment requirements. Of particular importance was the decision taken in the 1960s by the Food Additive and Contaminants Sub-Committee and Advisory Committee not to classify pesticides as either food contaminants or additives. This decision meant that pesticides have subsequently been subject to pesticide-specific regulation that was mutually constructed and agreed upon by government and industry.

Current statutory regulation was shown as having evolved through a succession of voluntary agreements. A key driver in the government's decision to maintain voluntary practices was internal concern over a lack of resources and toxicological expertise, and a worry that moving to statutory controls would mean proposing regulatory limits that were politically rather than scientifically motivated. A key assumption on the part of government was that under voluntary controls both industry and pesticide users would act responsibly and adhere to good practice.

However, Health and Safety Executive literature indicates that even in the late 1970s manufacturers could not be relied upon to adequately label their products and farmers could not be relied upon to take notice of warnings. Similar findings to these have been previously discussed by

Irwin (1995), who in researching the herbicide 2,4,5-T argued that the ACP's focus on the "recommended way" and "recommended purposes" was often at odds with reality. Notably, Irwin's case study is a clear example of the historic reluctance (also evidenced in this thesis) of the ACP to consider evidence alternative to that provided by regulatory sources. Indeed, this thesis is clear in showing that not only is the type of evidence that is deemed acceptable for regulation and review by committees such as the ACP rooted in the historical background of English pesticide regulation but so to is the type of expert required to assess such evidence, a matter that was discussed in Chapter Seven.

In this sense, the historical preference for certain types of evidence and toxicological expertise can be seen to have directly shaped the composition and role of pesticide committees working today, such as the ACP, which with the exception of its annual public meeting still holds its discussions in private on the grounds that meetings frequently contain confidential commercial information. This closed approach has been widely criticised by those outside of the advisory process and by the RCEP. Importantly, it can be directly contrasted to other committees in the food safety area such as the Spongiform Encephalopathy Advisory Committee (SEAC), whose Code of Practice states that with the exception of the discussion of confidential literature all advisory meetings should be held in public (SEAC, 2009). Although the ACP remains in line with the most recent Code of Practice for Scientific Advisory Committees (Government Office for Science, 2007), where recommendation 101 simply states that committees should aim to hold open meetings on a regular basis, interview data from ACP members suggests that the ACP

evoke recommendation 54 - “The proceedings of the committee should be as open as is compatible with the requirements of confidentiality” – as justification for why the more regular meetings should remain closed. In several interviews, ACP members noted that the recent review of ACP meeting practices concluded that it would be too disruptive to allow public access to the regular meetings; the public would have to frequently be asked to leave to ensure commercial confidentiality. It should be noted that this conclusion was not endorsed by all interviewed ACP members, several of whom felt that more could be done to increase the transparency of the Committee, suggesting that the recent ACP review was perhaps overly cautious in its attitude towards greater transparency and didn’t reflect the wishes of the whole committee.

Lastly and most importantly, in Chapter Four I demonstrated that despite scientific progress, the questions that we are asking about pesticide risks have remained unchanged since the risks were first considered 60 years ago. In particular, I evidenced that serious concerns were raised in the 1950s relating to chronic exposure to low-levels and exposure to mixtures of pesticides and that despite these concerns being repeatedly aired since this period they appear to have been persistently bracketed within the assessment and regulatory process, and hence effectively removed from the remit of pesticide advisory bodies such as the ACP. In subsequent chapters, I moved on to consider how and why this happened.

8.23 Management of uncertainty in the risk assessment of pesticide residues

In Chapter Five, using a combination of documentary evidence and interview data I sought to answer the second research question: *How are the potential risks of pesticide residues in food assessed in the current advisory system for regulation and why has this system been challenged?*

The chapter focused on hazard characterisation, highlighting the historical reliance on and privileging of *in vivo* methodology in pesticide assessment and the challenges this poses in respect of the validity of statutory reference doses. Methodological choice was shown to be partially subjective and intrinsically shaped by historic, social and pragmatic considerations regarding what is actually measurable or observable. This finding therefore supports that of Wynne (1992) and Irwin *et al.* (1997, p. 24) who have previously written that the science used in pesticide regulatory risk assessment is not wholly objective and is likely to include a mix of science, expert judgement and social and political values; factors that they argue may not always be explicit when safety standards are set.

In this chapter I used the evidence to suggest that there is a culture within pesticide risk assessment that encourages the minimisation of Type 1 errors to avoid the possibility of over-regulation. I also suggested that there is both a lack of awareness and lack of scope within the current system to consider Type 3 errors. I argued that this and the reliance on animal testing in toxicology has tangible consequences as it suggests that the current narrow characterisation of risk using data primarily collected from *in vivo* methods can only ever be a proxy for the actual level of risk,

which is currently indeterminable, a point that I suggest is not always transparent in decision-making processes.

The move towards evidence standardisation was discussed and I argued that while standardising regulatory requirements should in theory lead to increasingly transparent and rigorous assessments, in practice it acts to devalue evidence which is produced outside of the official process and limit its impact on decision-making – advisory bodies are simply not able to consider it, as it is classed as unacceptable for regulatory purposes. This finding suggests that this move is likely to be problematic in more fringe areas, such as mixtures toxicology, which often utilise newer, non-validated methods. Thus, I showed that there is a tension present in pesticide regulatory science: on the one hand, there is the widely acknowledged need for standardisation in order to produce robust regulatory evidence, and on the other, there is the need for the field to evolve in its scientific understanding which requires the capacity to think "outside the box" and consider new techniques that are yet to be standardised.

A recurring interview theme discussed within this chapter related to the limitations of obtaining evidence pertaining to the effects of pesticides in real life situations and how decisions therefore have to be taken in the knowledge that there is a degree of uncertainty. I showed that there is a perception among NGOs and some previous members of government that the ACP is reluctant to acknowledge this uncertainty in its decision-making process and that it uses this lack of certainty as an argument to maintain the status quo. Applying Shackley and Wynne's (1996)

examination of boundary-ordering devices, I suggested that the ACP may deny the possibility of uncertainty in its assessments so as not to undermine the current regulatory system in which it is embedded and hence its own epistemological authority. This becomes particularly relevant in the case of uncertainty arising from real life exposure, where it is increasingly recognised in both the scientific and policy literature that humans are frequently exposed to mixtures of pesticides, as opposed to individual substances. Despite this the ACP are however shown in this chapter and throughout this thesis to persistently bracket these concerns and so exclude these potential risks from assessment discussions.

Due to this persistent bracketing pesticide substances remain largely assessed on an individual basis so that potential effects from exposure to multiple pesticides are not routinely addressed within the risk assessment process. Drawing on both published literature (van Zorge, 1996; IPCS, 2001; Committee on Toxicity, 2002b) and interview data it was shown that this area has historically received limited attention within the regulatory and risk advisory community for two key reasons. First, there is a perception among regulators and scientists that the science is difficult to conduct and that the area is too complex to regulate; secondly, there is a belief that exposure to mixtures is a non-issue when individual components are present at otherwise acceptable levels. Where mixtures have been considered I discussed how researchers have typically favoured undertaking simple studies that have focussed on additivity as opposed to synergism, typically using binary mixtures at relatively high doses with acute toxicities and endpoints, situations which do not reflect real life exposure (El-Masri *et al.*, 1997; Committee on Toxicity, 2001).

This suggests that within the current risk assessment paradigm the true scale of uncertainty regarding the risks from exposure to mixtures is indeterminable and therefore potentially inadequately addressed by committees such as the ACP.

The evidence presented in this chapter regarding the assessment of pesticide mixtures therefore supports the findings of other STS researchers such as Wynne (1992) who have argued that the pervasion of pragmatic choices in toxicological studies has the effect of artificially reducing uncertainty. A key problem of this action, as noted by Wynne (ibid), is that once uncertainty has been removed it becomes difficult to reintroduce at a later stage of assessment and analysis. In effect, I therefore argued that the reluctance to address the issue of mixtures at a scientific level has resulted from it being bracketed and omitted from risk assessment discussions and the production of risk advice by bodies such as the ACP, a subject that I turned to in the next chapter.

8.24 Fragmentation of government advice on pesticide risks

Chapter Six considered the stage following risk assessment. There are now several government advisory bodies involved in the assessment of pesticides, with each applying its own conceptual framework with which to assess and advise on risk. In this chapter, I showed how this has resulted in increasing tensions between advisory bodies and a proliferation of advice that is not always compatible.

Using three case studies surrounding different types of pesticide exposure (pesticide mixtures, food residues, crop spraying and bystander exposure) the emerging tensions found between the official advisory system for pesticide regulation, as typified by the ACP, and other government bodies involved in assessing risk and providing advice were examined, with specific reference to how these conflicts have been managed. In doing so I answered the third research question: *How do different advisory bodies use scientific studies of risk assessment to produce advice on the risks of pesticides and pesticide residues?*

The case studies suggested that there is a fundamental difference in how the ACP frames the risk from pesticides when compared to those actors outside of the policy process. Government risk advice was shown in these examples to reflect areas of greater scientific certainty where causality between exposure and effect has been established. Conversely, advice from NGOs was shown to typically be more precautionary reflecting areas of greater uncertainty, where causality is yet to be officially established; a situation that is not unique to pesticides and is mirrored in other cases of environmental health regulation. For example, similar tensions can be seen surrounding the advice from government and NGOs relating to electro-magnetic radiation exposure from mobile phones and phone masts (Health Protection Agency, 2009; Powerwatch, 2009). Here, there is continued controversy surrounding potential effects of exposure, with NGO groups such as Powerwatch drawing on a range of scientific studies to advocate and advise on methods of reducing exposure. The Health Protection Agency (2009) itself highlighting that “it is not difficult to find contradictory results in the literature”. However, the following excerpt

from its advice suggests that it, like the ACP and PSD, is constrained in the evidence it is permitted to use in setting regulatory limits: “included in the scientific review are biological effects that might have health consequences, but whose existence has not been confirmed and which cannot be used to develop numerical restrictions on exposure” (Health Protection Agency, 2009). This, like the evidence presented on pesticide disputes suggests that so long as these framings are diametrically opposed the two groups are unlikely to agree on how to manage any risks from pesticides.

In the first case study, advice surrounding exposure to mixtures of pesticides was considered. Here, it was highlighted that the WiGRAMP – the working group charged with reviewing evidence – has been widely criticised for failing to give due weight to the uncertainty involved in risk assessment and the regulatory requirements that dictate the remit of pesticide assessments performed by the ACP in its report. As such the credibility of the resultant advice has been publicly challenged by both those within and outside government. In the second case study that explored the advice surrounding consumption of residues, it was shown that the differences in how the ACP and the FSA frame pesticides has resulted in a tension between the two bodies. However, these tensions were reduced by the FSA changing its position to match that of the ACP. One consequence was that this encouraged a proliferation of advice from those external to the official advisory process, who have been overtly critical of the ACP’s guidance and have subsequently sought to undermine the FSA’s credibility through suggesting that in aligning with the ACP the FSA has failed in its mandate of putting the consumer first. The third case

study discussed how the report and recommendations produced by the RCEP on bystander exposure were largely dismissed by other government advisory bodies. This was because they were seen to be too precautionary and at odds with the current assessment process and wider understanding of bystander risk from crop spraying. As such the advice and recommendations produced by the RCEP were sidelined by the government who favoured the views expressed by the ACP.

When viewed as a whole the evidence from the three case studies suggested that while the ACP has now begun to accept the possibility of effect from exposure to pesticide mixtures through independent action or simple additivity (note only in the cases where multiple substances are combined in one product), it appears to systematically neglect the possibility of synergism, a position that has been strongly criticised by the RCEP and NGOs. While the ACP was shown to publicly reject this criticism, the evidence presented throughout this thesis suggests that the RCEP was justified in making such critical remarks. Indeed, it suggests that the more reflexive approach to risk assessment as adopted by the RCEP is epistemologically superior to that of the ACP's, which appears to consistently fail to account for differences in perspectives regarding approaches to risk assessment and the management of uncertainty.

All three case studies illustrated that advisory bodies working in this area recognise that there are limitations in the ability to determine causal effects using the current evidence base. Despite this, there are questions surrounding the extent to which these limitations are acknowledged within risk assessment and the production of risk advice by bodies such

as the ACP. In all of the case studies, it is suggested by the actors involved that uncertainty and ignorance can be reduced through further research; a solution that is not, as others in the field of STS have shown, always guaranteed to be effective (Wynne, 1992; Sarewitz, 2004). However, in the case of pesticides I described how these calls have been resisted on the grounds that they would be resource intensive and not necessarily guaranteed to provide further information. It is therefore sometimes explicitly but more commonly implicitly accepted by these bodies that advice has to be formulated on the basis of incomplete evidence and in the knowledge that there are areas of uncertainty and ignorance.

The case studies empirically demonstrated the importance of institutional practices in the framing of risk advice. Indeed, I argued that such practices not only act as frames but also as boundary objects that help establish which risk questions are acceptable to ask and determine which evidence is acceptable for use in providing answers. I suggested that the official regulatory framework is therefore an anchoring device that acts to create consensus across advisory bodies and constrain alternative interpretations (van der Sluijs et al., 1998).

Many of these points have been discussed within the regulatory science literature in STS. For example, Jasanoff (1991, p.29) has argued that where there is uncertainty or ambiguity in scientific knowledge used for policy then “facts alone are inadequate to compel a choice”. In such situations evidence selection will blend both scientific and policy considerations, with the result that policy-makers are required to seek

something other than science to legitimise the choice of evidence used in risk decisions and subsequent advice. While this was shown to reflect the situation in pesticide assessment I noted the potentially misleading nature of Jasanoff's statement - even where the science seems clear, the evidence presented in this thesis and in previous STS literature suggests that underlying tacit assumptions remain, suggesting that the science used in risk assessment is rarely wholly independent of socio-political assumptions and community norms even when uncertainty and ambiguity is considered to be low.

One way in which many working in the field believe legitimacy is achieved in risk assessment and the production of advice is through the utilisation of those considered as 'experts' in the domain. However, the evidence presented in this thesis suggests that this leverage can lead to tensions between different expert groups as they compete to gain authority in an increasingly overcrowded arena; in this respect, the appeal to expertise as a way of dealing with the limitations of science was not always seen as successful. The themes of epistemic authority, expertise and legitimacy and the distinction between the right and wrong kind of expert were seen extensively in the interviews with advisory body members and were discussed in the following chapter.

8.25 Re-constructing the legitimacy of scientific experts in the post-BSE era

Having previously illustrated that the production of risk advice can lead to tensions not only between government bodies and NGOs but also

between different bodies within government, I explored the factors that underlie these differences; perceptions of expertise, trust and epistemic authority. Chapter Seven therefore addressed the final research question: *How are competing claims for scientific expertise and for lay involvement in risk assessment being handled in the case of pesticide residues?*

I have shown throughout this thesis that the area of pesticide risk assessment and management is complex with tensions remaining between those committees and experts who value in-depth specialist knowledge and those who place value on the use of broader, more generalist expertise in risk assessment. Such tensions, as epitomised by the distinction Collins and Evans (2002) make between *contributory* and *interactional* expertise, means that it is no longer enough for the government to simply appoint "the great and the good" in order to create legitimacy in risk decision making (Jasanoff, 1997b).

I argued that the *right* type of expertise has remained narrowly defined within the ACP, illustrating that the majority of ACP members believed that certain types of formal expertise were necessary to assess the often complex information found within the pesticide risk literature. The expertise that appeared to be most highly valued among this group was shown to be toxicological; a finding that suggests the historic privileging of toxicologists in the pesticide regulatory community persists, the effect of which is that other forms of expertise are either excluded from or play only a minor role in the ACP's discussions. The emphasis the ACP place on a focussed contributory style expertise, as embodied in toxicologists, can be seen as a direct contrast to the RCEP, which has argued that to truly

understand and manage risk there needs to be a move towards diverse advisory membership, that contains a greater degree of interactional expertise, to facilitate a broader and more holistic consideration of a topic.

I argued that despite a purportedly transparent advisory appointment framework there remains a perception among NGOs, some advisory members and members of government that groups such as the ACP are dominated by a small group of scientists, who share a similar value system and whose judgements can be difficult to challenge by those who are not considered to have the appropriate expertise. I proposed that this can lead to groupthink and the reluctance to challenge or question the status quo. I suggested that this may be linked to a desire within the ACP to present assessment findings and advice as being consensual, thus perpetuating the myth that science speaks with one voice (Collingridge and Reeve, 1986) and that consensus is required to ensure credibility.

To address the problem of groupthink, theories such as Beck's reflexive scientisation (Beck, 1992) advocate a de-monopolising and democratisation of science that would allow wider participation in risk decisions. Post-BSE it has been common within UK advisory committees to ensure that decisions surrounding risk and advice, are not only transparent but include the input of non-experts or lay people. However, I found that there are tensions surrounding not only the role of lay people on committees but whether such people can actually be considered as lay at all.

Those sitting within the advisory committees under study were found to typically regard the presence of lay members in three non-exclusive ways: first, that their presence was an irritant as it dumbed down discussion and suggested that they as experts could not be trusted; secondly, that they were helpful in assisting the experts consider issues from a consumer perspective; thirdly, that they were welcome as it highlighted to a wider audience the hard work of the expert members. In all categories my research indicated that lay members, although fully appointed members of the committee, were presented and considered by 'expert' members as being *outside* of the decision-making process, which was viewed as the preserve of experts.

The evidence also suggested that there is often a paradox in the appointment of lay members, as although appointed as 'lay' they often possess considerable expertise. In particular, I suggested that while they are often publicly appointed to act as the 'innocent' public (Irwin, 2006) they can frequently be characterised as possessing interactional and sometimes even contributory expertise (Collins and Evans, 2002). Indeed, they often appear to be selected specifically because of these attributes, as there is recognition that membership of advisory committees requires certain skills that would be absent in the 'innocent' citizen. However, once appointed they were often not recognised as expert within the committee structure.

Many of those that were included as lay members were employees of NGOs working in pesticide related fields. Previously, it has been argued that while NGOs can be identified as organisationally different from

'unorganised' citizens (Breckenridge, 1999), they are included in policy-making exercises not because they possess expertise, but because they represent a particular value system that is shared by their members or indeed they are included due to both reasons. In this sense, I showed that they are often not viewed as experts but as representatives of public groups or movements. This view was seen in this research as it was found that many NGO members, despite having scientific qualifications and subject expertise, were asked to join committees to represent the view of the wider non-expert public. Additionally, there was a perception among many 'expert' members that lay members should feed back their role to the public. However, I questioned to what extent this is possible given the strict codes of conduct that members must adhere to in respect of confidentiality. This research also suggested that NGO members have relatively little capacity to challenge the framing of the debate in terms of scientific evidence given the significant embedding of scientific expertise within such organisations.

It would be easy as Irwin (2006, p.316) has previously suggested to conclude that "there is little evidence that public talk has brought about a wider cultural and institutional transformation". However, the research shown in this thesis suggests that such a conclusion does not reflect the nuance of the situation; although wider participation in the field of pesticide risk assessment appears from this analysis to be limited in scope, it can still be described as a progression from previous models. However, until alternative forms of expertise are recognised as legitimate it will remain difficult for those outside of the dominant expert group to make any real impact in committees such as the ACP.

8.3 Policy implications

Within this thesis I have sought to discuss the challenges present in the assessment and advisory process around pesticide residue risks as conceptualised by those working within and outside it. However, in bringing this evidence together it is possible to now become less epistemological neutral and make suggestions as to the wider implications of my findings. Although derived from this specific piece of research these implications and more specifically the areas for further reflection as discussed in 8.31, have been influenced by the STS framework that I have been working within.

The evidence I have collected and analysed suggests that are real concerns surrounding the current limitations of the risk assessment process, most notably surrounding the ability of the dominant toxicological paradigm to account for those types of exposure that are not routinely covered by regulatory requirements, such as chronic low-level exposure and exposure to mixtures. These findings suggest that there are both known and indeterminable areas of uncertainty and hence potential areas of risk that are simply unaddressed by the current system. Interestingly however, the evidence suggests that the problem is not that such issues are wholly unrecognised but that they are and yet remain persistently bracketed by advisory bodies such as the ACP, which repeatedly denies the need to change current practices despite being frequently presented with evidence to the contrary.

I noted that a key difficulty faced by advisory bodies in instigating change is the external constraint imposed upon them through working within a statutory framework prescribing what counts as acceptable evidence. The result is that regulatory framing has at times acted to artificially reduce uncertainty in the risk assessment process through omitting discussion of the more complex scenarios that are outside of the current regulatory remit. This in turn encourages a false level of confidence regarding risk to be projected by advisory bodies as they have not had to consider all potential exposure scenarios. Such a situation increases the difficulty of presenting alternative and conflicting views as credible, a particular problem for those suffering from illnesses believed to be caused by exposure to low-levels of pesticide mixtures where it is often difficult to demonstrate a clear causal pathway between exposure and effect. This type of situation is also compounded by the fact that these issues are not routinely addressed within pesticide risk assessment and so there is little regulatory literature available to support their claims. My evidence suggests however, that despite at times acknowledging the limitations of working within a statutory framework, there appears little desire from many members of the ACP to challenge and question existing practices, suggesting that there is unlikely to be any major changes in the assessment process in the near future in relation to the assessment of mixtures, unless dictated down by the European Union.

It might be presumed from the discussion so far that the problem of uncertainty in the risk assessment of pesticide residues can be ‘solved’ simply through the introduction of newer methods, such as toxicogenomics (Boobis, 2007) and physiologically based

pharmacokinetic/ pharmacodynamic modelling (El-Masri *et al.*, 1995), that purport to make easier the assessment of exposure to low-levels and more complex mixtures and their effects, such as synergism and antagonism as opposed to simple additivity. However, I would call upon previous STS studies to suggest that all scientific assessments, especially those in the regulatory arena, will inevitably be framed by prior assumptions (that might be externally challenged) and socio-political values that may be more or less transparent to the external observer (Shackley *et al.*, 1998; Sarewitz, 2004; Sarewitz *et al.*, 2004). In this sense, there is no escape from uncertainty or differences between scientific styles. Indeed, it has been argued within STS that risk assessment is intrinsically characterised by uncertainty (Wynne and Mayer, 1993; Levidow, 2003) - a finding that is supported by this research - therefore uncertainty often does not arise from inadequate knowledge but is a reflection of the underlying questions asked by the scientists and regulators and their selection of relevant facts, which have been shown in this thesis and previous STS literature to frequently be based on value choices (van Zwanenberg and Millstone, 2000; Jensen and Sandøe, 2002; Ravetz, 2002; Levidow, 2003).

As such, the evidence presented in this thesis supports the arguments made in previous STS research in the fields of regulatory science and science-based policy-making to suggest that the real challenge for risk assessment and advice is actually about being open and aware of these different frameworks and successfully handling their implications. To do this however, the evidence presented in this thesis suggests that it is imperative that known uncertainties are acknowledged and the

boundaries of knowledge and understanding are fully considered and publicly reported. The evidence indicates that this would require a complete culture change within bodies such as the ACP, which appears to be locked into an un-reflexive mode of working that assumes the current system is adequate in assessing risk and protecting human health in order to protect its own epistemological authority in this advisory domain.

This thesis does not attempt to validate the scientific merit of evidence that is currently not accepted as legitimate in risk discussions. Nor does it seek to place value on different types of expertise. However, the evidence that I have gathered suggests that the very narrow focus on pesticide risk and its management, as epitomised by the ACP, severely limits the potential for a wider, more holistic consideration of what risks pesticides may pose and how these could be managed in the future. It is here that the evidence and expertise that is currently considered as unsuitable for regulatory purposes could be used to help frame these discussions. Indeed, a key argument made within the thesis is that uncertainty and risk is often not due to an inadequate amount of research but a result of how a problem has been initially framed; the wrong questions being asked or the wrong methodology being adopted to answer such questions. Such arguments have been previously recognised by those such as Wynne (1992, p.113) who suggests that risk assessment practices can artificially reduce uncertainties through imposing “man-made intellectual closure around entities which are more open-ended than the resulting [scientific] models suggest”. As such, he argues that routinisation of practice can render these uncertainties invisible to risk assessors and that it is only through “intense and open examination of

the scientific evidence and competing scientific interpretations" that these uncertainties and their consequences can be understood. The evidence presented in this thesis therefore suggests that by broadening both the evidence base and the expertise to include alternative forms of knowledge and understanding, the possibility of Type 3 errors in risk assessment and management may be reduced.

At the heart of the matter is the question of whether to be effective and legitimate advisory committees require contributory or interactional expertise, or a combination of both? This question has been previously discussed within the STS literature with Jasanoff arguing that: "The most valued expert is one who not only transcends disciplinary boundaries and synthesises knowledge from several fields but also understands the limits of regulatory science and the policy issues confronting the agency" (Jasanoff, 1990, p.243). In her U.S. study, The Fifth Branch, Jasanoff (ibid) suggests that the blurring of boundaries between scientists and regulators can actually result in increasingly productive policy-making. The evidence presented here suggested that within UK pesticide advisory committees no such balance has been successfully achieved. This was seen to be particularly true in the case of the ACP which strongly advocates the involvement of a very narrow range of expertise in risk assessment. However, I would argue that its approach is epistemologically inferior to that of the RCEP's, as unlike the RCEP the ACP appears to consistently fail to account for differences in perspectives regarding approaches to risk assessment and the management of uncertainty

The findings here support Irwin's (2006, p.315) observations that there is a "considerable lack of clarity" surrounding the relationship between expert and lay involvement and hence unresolved questions remain surrounding the epistemological status of different voices. Given the wide scale move within the UK for greater democratisation of scientific advisory committees, the findings presented within this thesis suggest that these questions need to be better addressed before any positive effect of widening participation will be observed. Without this there is a danger that the appointment of lay participants will be viewed as tokenistic, which would undermine the initial goal of increasing legitimacy. Similarly, the goal of greater transparency has only partially been met within those committees examined here. If greater transparency is a desired feature of British policy-making then greater attention needs to be paid to how this can be practically achieved. It is not enough to rely on rhetoric that the role of lay members is to feedback their experiences to the public. If no formal process is established then such public communication will not occur and the advisory process will remain closed.

8.31 Areas for further reflection

Following a review of the evidence presented in this thesis and consideration of how this research relates to other similar research in the field of STS I have identified a number of areas in the current risk assessment process that could be better managed if the issue of pesticide mixtures and other related risks are to be more adequately addressed. The five key points as identified by this thesis are discussed below:

1) In relation to the specific issue of exposure to mixtures, the ACP should better acknowledge the current limitations in its risk assessment process and take steps to address them. In particular, consideration should be given to how it could reasonably move towards the use of integrated approaches that consider realistic multi-chemical, multi-route exposure scenarios as advocated by those such as the IPCS (2001).

2) There is a need within pesticide risk assessment and potentially chemical risk assessment more generally, to make clear to risk managers and the wider public where there are areas of uncertainty and indeterminacy. This point has been previously recognised by the RCEP in its report “Setting Environmental Standards” where it is noted that:

> Scientific assessments should indicate clearly where the boundaries of knowledge lie. To be helpful to policy-makers they should indicate clearly what is known or considered to be indisputable and what is considered to be speculative. (RCEP, 1998, paragraph 2.75)

3) There is also a need for clearer boundaries to be defined between risk assessment and risk management practices as the evidence presented in this thesis suggests that in practice they are frequently blurred and often opaque to external observers. Additionally, the reasoning behind risk management decisions should be explicit; it should be made clear

if and when risk decisions incorporate socio-political considerations and what the resultant effects may be.

4) The evidence presented in this thesis suggests that uncertainty can not simply be reduced through conducting more detailed research as its presence is intrinsically linked to the original framing of the issue and the questions that are posed at the beginning of the process. To reduce uncertainty and also Type 3 style errors there should be greater communication between advisory bodies and other stakeholders (including the wider public) in the early stages of risk assessment. This should not only help to increase the transparency of the process but provide opportunity for the development of a shared understanding of the issue and allow alternative view points and evidence to be openly discussed.

5) The role and remit of scientific advisory committees should be clarified to better understand what expertise is required in different circumstances and why. This would help identify and make more explicit the role individuals are expected to play. Consideration should be given to increasing the range of expertise on risk assessment committees so that a variety of theoretical and disciplinary positions are included; this may help to reduce the possibility of groupthink. Additionally, there should be greater discussion over the inclusion of 'lay' members and whether in actuality some form of expertise (interactional, contributory or procedural) is necessary in order to fully participate. Training could be provided to all committee members to ensure that they are all able to fully interact and participate when

working within a committee environment. Where there is an expectation that lay members should feed their involvement back to the public, adequate procedures should be put in place to do so.

8.4 Further research

There are a number of ways in which this thesis could be usefully taken further.

First, it would be interesting to undertake a comparative analysis with another group of widely used chemicals to explore the extent to which the characteristics of pesticide assessment and regulation are found elsewhere. An example would be to study the recent controversy surrounding the use of phthalates in baby bottles and children's toys. Phthalates are a group of synthetic chemicals that are typically used as plasticizers. While they have been widely used in a range of consumer products for the past 50 years, there has been growing concern among environmental and consumer NGOs that certain phthalates may act as endocrine disrupters affecting the development of animal and human reproductive organs (Friends of the Earth, 2001). Although organisations such as American Chemistry Council have argued that there is no convincing reliable data to suggest that phthalates pose a risk to human health (Phthalate Information Centre, 2005), many manufacturers have voluntarily removed them from their products amidst public concern. A comparative analysis would help draw out those features of the pesticide debate that are particular to pesticides, whilst providing an opportunity to

explore how uncertainty and chemical risk is managed in a more general manner.

Secondly, this research could be extended to exploring how the issues discussed in this thesis have been managed elsewhere using different regulatory methods. For example, it is recognised that since the introduction of the Food Quality Protection Act (FQPA) in the United States in 1996, the US Environmental Protection Agency is now required to consider the following in assessing and regulating pesticides (Environmental Protection Agency, 2008):

- the aggregate risk from exposure to a pesticide from multiple sources when assessing tolerances
- the cumulative exposure to pesticides that have common mechanisms of toxicity

It would therefore be of interest to look at the historical background to these developments and establish how the assessment and regulatory systems differs in the US from Europe, and what the implications are in terms of setting human reference doses for pesticides. This would further help to draw out and characterise those aspects of policy-making that are shaped by social values and expert judgement.

Similarly, in the UK a legal Judgement has been recently made in relation to a possible link between exposure to low-levels of atmospheric toxic waste from land reclamation in Corby and birth defects. In this case the Judge ruled that reclamation works were capable of leading to some, or

all, of the birth defects presented to the court, despite being carried out within health and safety rules at the time (Royal Courts of Justice, 2009). While this ruling does not state that the contaminants were definitively and causally responsible, it is unusual as it accepts the possibility that this might be the case and therefore allows further legal action to be taken against Corby Council for negligence. In many aspects the arguments made within this Judgement can be seen as parallel to those arguments presented in relation to the risks resulting from exposure to pesticides. In particular, paragraph 755 of the Judgement acknowledges that low-level exposure might be problematic:

> …embryos and foetuses are much more sensitive to toxic chemicals than adults. The dosage of a teratogen required to induce birth defects can be much lower than that which would be required to cause toxic effects in adults and, although its teratogenic effects may be the result of induction by high doses, they may also be induced by low level exposures. (Royal Courts of Justice, 2009)

Thirdly, during this research it became apparent that European harmonisation is having an unprecedented impact not only on how new pesticides are assessed and regulated, but also in deciding which of the older pesticides will remain available for use following re-evaluation. Several interviewees work within Europe and suggested that the level of toxicological expertise varies widely between member states. There would therefore be merit in exploring how and why expertise differs and what effect this may have on the risk assessment and the registration of

pesticide substances across Europe. Additionally, there was concern amongst interviewees that the new more stringent requirements under the European Plant Protection Products Regulations (PPPR) would result in many existing pesticide products being withdrawn following a re-examination. This was considered problematic for a variety of reasons including the possibility of the development of pesticide resistance through the over use of certain pesticides. It would therefore be interesting to explore how the changes in pesticide regulation may materially affect pest management strategies across Europe.

Finally, one of the key messages of this research is that without a holistic understanding of the problem it is difficult to ask the right questions and hence mitigate and manage risk. In this sense, the most interesting piece of further research would be to explore how pesticides could be practically considered among advisory bodies in a more holistic fashion. Different assessment and policy models could be explored to develop a workable framework that would allow the consideration of the wider issues surrounding human health, the environment, sustainability and food security in the assessment of pesticides.

References

Adorno, T., Albert, H., Dahrendorf, R., Habermas, J., Pilot, H. and Popper, K. R. (1976) *The Positivist Dispute in German Sociology*. Heinemann, London.

Advisory Committee on Pesticides (2002a) *Advisory Committee on Pesticides (ACP) Advice to the Food Standards Agency (FSA) on Washing and Peeling Fruit and Vegetables*. Available at: http://www.pesticides.gov.uk/acp.asp?id=592.

Advisory Committee on Pesticides (2002b) *Assessment of Risk to Bystanders*. Available at: http://www.pesticides.gov.uk/acp.asp?id=586.

Advisory Committee on Pesticides (2004a) *ACP's Chairman's assessment of the Ontario Review*. Available at: http://www.pesticides.gov.uk/acp.asp?id=1389.

Advisory Committee on Pesticides (2004b) *Final Minutes of the 307th meeting of the Advisory Committee on Pesticides held on 20 May 2004*. Available at: http://www.pesticides.gov.uk/acp.asp?id=1204.

Advisory Committee on Pesticides (2004c) *Minority Statement on the Pesticides Literature Review Published by the Ontario College of Family Physicians*. Available at: http://www.pesticides.gov.uk/acp.asp?id=1550.

Advisory Committee on Pesticides (2005) *Crop Spraying and the Heath of Residents and Bystanders: A commentary on the report published by the Royal Commission on Environmental Pollution in September 2005*. 30 December 2005. Available at: http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/ACP/RCEP_Response_vfinal.pdf

Advisory Committee on Pesticides (2008) *Advisory Committee on Pesticides: Terms of Reference*. Available at: http://www.pesticides.gov.uk/acp.asp?id=595.

Anon (2002 b) The Scientific Basis of Chemical Risk Assessment. *ATLA-Alternatives To Laboratory Animals*, **30** (S1): 21-25.

Appleton, J. V. and Cowley, S. (1997) Analysing clinical practice guidelines. A method of documentary analysis. *Journal of Advanced Nursing*, **25**: 1008-1017.

Ashford, N. and Miller, C. (1998) *Chemical Exposures: Low Levels and High Stakes*. Van Nostrand Reinhold, New York.

Ashford, N., Ryan, C. W. and Caldart, C. C. (1983) Law and Science Policy in Federal Regulation of Formaldehyde. *Science*, **222**: 894-900.

Bäckstrand, K. (2004) Scientisation vs. Civic Expertise in Environmental Governance: Eco-feminist, Eco-modern and Post-modern Responses. *Environmental Politics*, **13** (4): 695-714.

Baker, B. P., Benbrook, C. M., Groth, E. and Lutz Benbrook, K. (2002) Pesticide residues in conventional, integrated pest management (IPM)-grown and organic foods: insights from three US data sets. *Food Additives and Contaminants*, **19** (5): 427 - 446.

Barke, R. (2009) Balancing Uncertain Risks and Benefits in Human Subjects Research. *Science, Technology and Human Values*, **34** (3): 337-364.

Barnes, B. (1974) *Scientific Knowledge and Sociological Theory*. Routledge, London.

Barrett, D. (1997) *Fibromyalgia: An "invisible" Disability*. Available at: http://www.paintracking.com/fms03.html.

Beck, U. (1992) *Risk Society: Towards a New Modernity*. Sage Publications Ltd, London.

Becker, H. (1998) *Tricks of the Trade: How to Think about Your Research while Doing It*. University of Chicago, Chicago.

Bell, I., Baldwin, C., Fernandez, M. and Schwartz, G., E. R. (1999) Neural sensitization model for multiple chemical sensitivity: overview of theory and empirical evidence. *Toxicology and Industrial Health*, **15**: 295-304.

Benford, D. (2008) Risk - What is it? *Toxicology Letters*, **180** (2): 68-71.

Boobis, A. R. (2007) The future of mixture toxicology. *Toxicology*, **240** (3): 142.

Borland, K. (1991) "'That's Not What I Said': Interpretive Conflict in Oral Narrative Research". In: (Eds. Gluck, S. and Patai, D.) *Women's Words: The Feminist Practice of Oral History*. Routledge, New York.

Breckenridge, L. P. (1999) Nonprofit environmental organizations and the restructuring of institutions for ecosystem management. *Ecology Law Quarterly*, **25** (4): 692-704.

Brickman, R., Ilgen, T. and Jasanoff, S. (1985) *Controlling Chemicals: The Politics of Regulation in Europe and the United States*. Cornell University Press, New York.

British Crop Production Council (2006) *Royal Commission on Environmental Pollution Report on Crop Spraying and the Health of Residents and Bystanders: Commentary by the British Crop Production Council.*, Available at: http://www.bcpc.org/reports/docs/20060517.pdf.

British Medical Association (1992) *Pesticides, Chemicals and Health*. Edward Arnold. London.

Buckeley, H. and Mol, A. P. J. (2003) Participation and Environmental Governance: Consensus, Ambivalence and Debate. *Environmental Values*, **12** (2): 143-154.

Carlile, W. R. (2006) *Pesticides Selectivity, Health and the Environment*. Cambridge University Press, Cambridge.

Carson, R. (1962) *Silent Spring*. Penguin Books Ltd, London.

Casper, M. J. (2003) Introduction: Chemical Matters. In: (Ed. Casper, M. J.) *Synthetic Planet: Chemical Politics and the Hazards of Modern Life*. Routledge, London.

Cassell, J. (1978) 'Risk and benefit to subjects of fieldwork'. *American Sociologist*, **13**: 134-143.

Christiansen, S., Scholze, M., Dalgaard, M., Vinggaard, A. M., Axelstad, M., Kortenkamp, A. and Hass, U. (2009) Synergistic Disruption of External Male Sex Organ Development by a Mixture of Four Antiandrogens. *Environmental Health Perspectives*, **117** (12): 1839-1846.

Cohen, B. R. and Galusky, W. (2010) Guest Editorial. *Science as Culture,* 19 (1): 1-14.

Colborn, T. (2006) A case for revisiting the safety of pesticides: A closer look at neurodevelopment. *Environmental Health Perspectives*, **114** (1): 10-17.

Colborn, T., Dumanoski, D. and Peterson-Myers, J. (1997) *Our Stolen Future*. Plume Books, Washington.

Colborn, T., Saal, F. S. V. and Soto, A. M. (1993) Developmental Effects of Endocrine-Disrupting Chemicals in Wildlife and humans. *Environmental Health Perspectives*, **101** (5): 378-384.

Collingridge, D. and Reeve, C. (1986) *Science Speaks to Power: The Role of Experts in Policy Making*. Frances Pinter (Publishers), London.

Collins, H. M. (1988) Public Experiments and Displays of Virtuosity: The Core-Set Revisited. *Social Studies of Science*, **18** (4): 725-48.

Collins, H. M. and Evans, R. (2002) The Third Wave of Science Studies: Studies of Expertise and Experience. *Social Studies of Science*, **32** (2): 235-296.

Commission of the European Communities (2001) *White paper on a strategy for a future chemicals policy*. COM (2001) 88 final. Brussels.

Committee on Carcinogenicity and Committee on Toxicity (2006) *Statement on Royal Commission on Environmental Pollution: Crop Spraying and the Health of Residents and Bystanders*. COT/06/05 and COC/06/S1. Available at:
http://cot.food.gov.uk/pdfs/cotstatementrcep0605pdf

Committee on Toxicity (2001) *Abstracts of Oral Presentations for WiGRAMP open stakeholder meeting 17.04.2001*. Available at: http://www.food.gov.uk/multimedia/pdfs/wigrampstakeabs.pdf.

Committee on Toxicity (2002a) *Executive Summary of Draft WiGRAMP Report*. Food Standards Agency, London.

Committee on Toxicity (2002b) *Risk Assessment of Mixtures of Pesticides and Similar Substances*. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. Food Standards Agency. London.

Committee on Toxicity (2007) *Variability and Uncertainty in Toxicology of Chemicals in Food, Consumer Products and the Environment*. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. FSA. London.

Committee on Toxicity (2008) *Committee on Toxicity*. Available at: http://cot.food.gov.uk/.

Connor, S. (2002) *Fruit safe to eat without washing, say scientists.* The Independent, 27/03/2002. Available at: http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/fruit-safe-to-eat-without-washing-say-scientists-655535.html

Corburn, J. (2003) Bringing local knowledge into environmental decision making - Improving urban planning for communities at risk. *Journal of Planning Education and Research*, **22** (4): 420-433.

Cormode, L. and Hughes, A. (1999) The economic geographer as a situated researcher of elites. *Geoforum*, **30**: 299-300.

Cranor, C. F. (1993) *Regulating Toxic Substances: A Philosophy of Science and the Law*. Oxford University Press, Oxford.

De Marchi, B. (2003) Comments on Ortwin Renn's article: 'Hormesis and risk communication': considerations about uncertainty, ignorance and governance. *Human & Experimental Toxicology*, **22** (1): 25-29.

De Rosa, C., Richter, P., Pohl, H. and Jones, D. E. (1998) Environmental exposures that affect the endocrine system: public health implications. *Journal of Toxicology and Environmental Health*, **1**: 3-26.

Defra (2000) *Guidelines for Environmental Risk Assessment and Management.* London. Available at:
http://www.defra.gov.uk/environment/risk/eramguide/index.htm

Defra (2001) *Code of Practice for Independent Members of The Advisory Committee on Pesticides*. Supplementary to the Code of Practice for Scientific Advisory Committees (Department of Trade and Industry).

Defra (2002) *Guidelines for Environmental Risk Assessment and Management.*, Available at:
http://www.defra.gov.uk/Environment/risk/eramguide/03.htm.

Defra (2004) *News Release: Royal Commission to Examine Science on Human Exposure Risks from Crop Spraying*. Available at: http:www.defra.gov.uk/news/2004/040616d.htm.

Defra (2005) *Environmental Protection: Chemicals*. Available at: http://www.defra.gov.uk/environment/chemicals/eufuture.htm.

Defra (2006a) *Government publishes response to Royal Commission's Pesticide Report (20th July 2006)*. Available at: http://nds.coi.gov.uk/content/detail.asp?ReleaseID=215576&NewsAreaID=2&NavigatedFromSearch=True.

Defra (2006b) *The Royal Commission Environmental Pollution report on crop spraying and the health of residents and bystanders - Government response*. 14th June 2009. Available at: http://www.rcep.org.uk/reports/sr-2006-cropspraying/documents/rcepcropspray-response.pdf.

Defra (2007a) *Explanatory Memorandum to the Pesticides (Maximum Residue levels in Crops, Food and Feeding Stuffs) (England and Wales) (Amendment) Regulations*. Available at: http://www.opsi.gov.uk/SI/em2007/uksiem_20070971_en.pdf.

Defra (2007b) *Review of the Royal Commission on Environmental Pollution.* Consultant's report. Available at: http://www.defra.gov.uk/environment/rcep/pdf/report.pdf

Defra (2008) *Risk Analysis.* Veterinary Laboratories Agency, Available at: http://www.defra.gov.uk/vla/services/ser_risk.htm.

Defra, Environment Agency and Institute for Environment and Health (2000) *Guidelines for Environmental Risk Assessment and Management*. Available at: http://www.defra.gov.uk/environment/risk/eramguide/index.htm.

Defra and Health and Safety Executive (2005) *A Guide to Pesticide Regulation in the UK and the role of The Advisory Committee On Pesticides*. ACP 19 (311/2005). Available at: http://www.pesticides.gov.uk/acp_home.asp

Department of Education and Science (1967) *Review of the Present Safety Arrangements for the Use of Toxic Chemicals in Agriculture and Storage*. Report by the Advisory Committee on Pesticides and Other Toxic Chemicals. HMSO. London.

Desmond, M. (2004) Methodological challenges posed in studying an elite in the field. *Area*, **36** (3): 262-269.

Dickson, D. (1988) *The New Politics of Science*. The University of Chicago Press, Chicago.

Douglas, H. (2000) Inductive Risk and Values in Science. *Philosophy of Science*, **67** (4): 559-579.

Dumit, J. (2006) Illnesses you have to fight to get: Facts as forces in uncertain, emergent illnesses. *Social Science and Medicine*, **62** (3): 577-590.

Eden, S. (2005) Green, gold and grey geography: legitimating academic and policy expertise. *Transactions of the Institute of British Geographers*, **30** (3): 282-286.

Eden, S., Donaldson, A. and Walker, G. (2006) Green groups and grey areas: scientific boundary-work, non-governmental organisations, and environmental knowledge. *Environment and Planning A*, **38**: 1061-1076.

Eden, S. and Parr, D. (2006) *How do NGOs commission, communicate and contest science?* BA and ESRC Science in Society Seminars (June 6 2006). London.

Edson, E. F. (1958) Occupational Health Aspects Of Pesticides In Britain. *Occupational Medicine*, **8** (1): 24-29.

EEC (1991) *Plant Product Regulations*. Directive (91/414/EEC). Available at: http://eurex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!CELEXnumdoc&lg=EN&numdoc=31991L0414&model=guichett

El-Masri, H. A., Reardon, K. F. and Yang, R. S. H. (1997) Integrated approaches for the analysis of toxicologic interactions of chemical mixtures. *Critical Review of Toxicology*, **27**: 175-197.

El-Masri, H. A., Thomas, R. S., Benjamin, S. A. and Yang, R. S. H. (1995) Physiologically based pharmacokinetic/phamacodynamic modeling of

chemical mixtures and possible applications in risk assessment. *Toxicology*, **105** (2-3): 275-282.

Elliott, S. J., Cole, D. C., Kruger, P., Voorberg, N. and Wakefield, S. (1999) The power of perception: Health risk attributed to air pollution in an urban industrial neighbourhood. *Risk Analysis*, **19** (4): 621-634.

Entman, R. (1993) Framing Toward Clarification of a Fractured Paradigm. *Journal of Communication*, **43** (4): 51-58.

Environmental Protection Agency (2008) *Implementation of Requirements under the Food Quality Protect Act (FQPA)*. Available at: http://www.epa.gov/opp00001/regulating/laws/fqpa/fqpa_implementation.htm.

Europa (2005) *The precautionary principle*. Available at: http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.

European Centre for the Validation of Alternative Methods (2008) *About ECVAM*. Available at: http://ecvam.jrc.it/.

European Chemicals Bureau (2006) *Annex V (5), Part B, Methods for the determination of toxicity*. Available at: http://ecb.jrc.it/testing-methods/.

European Commission (2004a) *Communication from the Commission to the Council, the European Parliament and the European Economic and*

Social Committee: A European Environment and Health Strategy. Available at: http://ec.europa.eu/environment/health/pdf/x_sum.pdf.

European Commission (2004b) *Draft Commission Regulation of laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8 (2) of Council Directive 91/414/EEC*. SANCO/10157/2004 Rev. 6 (PVNA/2004/10157/10157R6-EN.doc). Brussels. Available at: http://ec.europa.eu/food/plant/protection/evaluation/review_programme_en.pdf

European Commission (2006) *Special Eurobarometer 238 (2005): Risk Issues*. Available at: http://ec.europa.eu/food/food/resources/special-eurobarometer_riskissues20060206_en.pdf.

European Commission (2008) *Laboratory Animals: Revision of Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes*. Available at: http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm

Eyerman, R. and Jamison, A. (1989) Environmental knowledge as an organisational weapon: the case of Greenpeace. *Social Science Information*, **28**: 99-119.

FAO (1986) *International code of conduct on the distribution and use of pesticides*. UN. Food and Agriculture Organisation of the United Nations. Rome.

FAO (1995) *Codex Alimentarius: how it all began*. FAO celebrates 50 years. Available at: http://www.fao.org/DOCREP/V7700T/V7700T09.HTM

FAO and WHO (2006) *Codex Alimentarius*. Available at: http://www.codexalimentarius.net/web/index_en.jsp.

Feron, V. J., Cassee, F. R., Groten, J. P., van Vilet, P. W., van Zorge, J. A. (2002) International Issues on Human Health Effects of Exposure to Chemical Mixtures. *Environmental Health Perspectives*, **110** (S6): 893-899.

Festing, M. (2000) Doing better animal experiments; together with notes on genetic nomenclature of laboratory animals. *ANZCCART News*, **13** (3): 1-8.

Food Standards Agency (2002a) *The Food Standards Agency: Statement of General Objectives and Practices*. Available at: http://www.food.gov.uk/multimedia/pdfs/sgop.pdf.

Food Standards Agency (2002b) *What do people mean when they talk about a 'cocktail' effect in relation to pesticides?* Available at: http://www.food.gov.uk/safereating/chemsafe/pesticides/pesticidesmainqa/pesticidesqaq04.

Food Standards Agency (2004a) *Do I need to wash and peel fruit and vegetables to remove pesticide residues?* Safety and Hygiene. Available at:

http://www.food.gov.uk/safereating/chemsafe/pesticides/pesticidesmainqa/pesticidesqaq10.

Food Standards Agency (2004b) *Your questions on pesticides*. Safety and Hygiene. Available at: http://www.food.gov.uk/safereating/chemsafe/pesticides/pesticidesmainqa/#h_407659.

Food Standards Agency (2005) *Action Plan on the Risk Assessment of Mixtures of Pesticides and Similar Substances*. Available at: http://www.food.gov.uk/multimedia/pdfs/WiGRAMPActionPlan0305.pdf.

Food Standards Agency (2008) *Mixtures: Toxicology and Exposure Research Programme (T10)*. Available at: http://www.food.gov.uk/science/research/researchinfo/foodcomponentsresearch/mixturesresearch/t10prog/.

Friends of the Earth (2001) *Press Briefing: Chemicals and Health*. Available at: http://www.foe.co.uk/resource/briefings/chemicals_and_health.pdf.

Friends of the Earth (2002a) *Chemicals in Household Products - What the manufacturers told us*. Chemicals in Household Products - What the manufacturers told us. London. Available at: http://www.foe.co.uk/pubsinfo/pubscat/reports.html#safer

Friends of the Earth (2002b) *New pesticide cocktail report admits concerns*. Available at: http://foe.org.uk/campaigns/real_food/news/2002_october_october_15.html.

Friends of the Earth (2002c) *Pesticides still in food*. Available at: http://foe.org.uk/campaigns/real_food/news/2002_november_november_12.html.

Friends of the Earth (2004a) *Children's Exposure to Pesticides in Apples and Pears*. Available at: http://www.foe.co.uk/resource/media_briefing/pesticidesandtoddlers.pdf.

Friends of the Earth (2004b) *Latest results reveal a cocktail of pesticide exposure*. Available at: http://www.foe.co.uk/resource/press_releases/latest_results_reveal_a_co_03032004.html.

Friends of the Earth (2004c) *Toddlers Exposed to Daily Pesticide Threat*. Available at: http://www.foe.co.uk/resource/press_releases/toddlers_exposed_to_daily_29072004.html.

Fryer, M. E., Collins, C. D., Colville, R. N., Ferrier, H. and Nieuwenhuijsen, M. N. (2004) *Evaluation of currently used exposure models to define a human exposure model for use in chemical risk assessment in the UK*.

The Interdepartmental Group on Health Risks from Chemicals. Imperial College London. London. Available at: http://www.silsoe.cranfield.ac.uk/ieh/pdf/mark_niewenhuijsen_finalreport.pdf

Funtowicz, S. O. and Ravetz, J. R. (1993) Science For The Post-Normal Age. *Futures*, **25** (7): 739-755.

Gibbons, M., Limoges, C., Nowotny, H., Schwartzman, S., Scott, P. and Trow, M. (1994) *The New Production of Knowledge*. Sage, London.

Gieryn, T. F. (1983) Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists. *American Sociological Review*, **48** (6): 781-795.

Gieryn, T. F. (1995) Boundaries of Science. In: (Eds. Jasanoff, S., Markle, G. E., Petersen, J. C. and Pinch, T.) *Handbook of Science and Technology Studies*. Sage, London.

Gieryn, T. F. (1999) *Cultural Boundaries of Science: credibility on the line*. University of Chicago Press, London.

Gilbert, D. (1987) *Pesticide Safety Policy and Control Arrangements in Britain.* Imperial College of Science and Technology, University of London. London.

Gilbert, D. and Macrory, R. (1989) *Pesticide Related Law: A guide to Pesticide Related Law in the United Kingdom with an Historical Review of the Development of Pesticide Safety Policy*. The British Crop Protection Council, Farnham, Surrey.

Gilbert, N. and Mulkay, M. (1984) *Opening Pandora's Box: A sociological analysis of scientists' discourse*. Cambridge University Press, Cambridge.

Gillespie, B., Dave, E. and Johnston, R. (1979) Carcinogenic Risk Assessment in the United States and Great Britain: The Case of Aldrin/Dieldrin. *Social Studies of Science*, **9** (3): 265-301.

Gitlin, T. (1980) *The Whole World is Watching: Mass Media in the Making and Unmaking of the New Left*. University of California Press, Berkeley, CA.

Goffman, E. (1974) *Frame Analysis: An essay on the organization of experience*. Harvard University Press, Cambridge, MA.

Government Office for Science (2007) *Code of Practice for Scientific Advisory Committees*. Department for Innovation, Universities and Skills. Available at: http://www.dius.gov.uk/office_for_science/science_in_government/strategy_and_guidance/~/media/publications/F/file42780

Green, M. B. (1995) *A Short History of the Pesticides Group 1954 - 1994*. Society of Chemical Industry. London.

Gudmundsdotter, S. (1996) The Teller, the Tale, and the One Being Told. *Curriculum Inquiry*, **26** (3): 293-306.

Guston, D. H. (2001) Boundary Organizations in Environmental Policy and Science: An Introduction. *Science, Technology & Human Values*, **26** (4): 399-408.

Guston, D. H. (2004) Forget Politicizing Science. Let's Democratize Science! *Issues in Science and Technology*, **Fall**: 25-28.

Hajek, A. E. (2004) *Natural Enemies: An Introduction to Biological Control*. Cambridge University Press, Cambridge.

Hajer, M. A. (1995) *The Politics of Environmental Discourses: Ecological Modernization and the Policy Process*. Oxford University Press, Oxford.

Halffman, W. and Hoppe, R. (2002) *Rethinking Political Judgement and Science-based Expertise*. Research Protocol.

Hammersley, M. (1992) The generalisability of ethnography. In: (Ed. Hammersley, M.) *What's wrong with ethnography?* Routledge, London**:** 85-95.

Hansard (1996) *Lords Sitting of 6 February 1996. Agriculture: Health & Safety Responsibilities*. Available at: http://hansard.millbanksystems.com/lords/1996/feb/06/agriculture-health-safety.

Hansard (2000) *Fruit and Vegetables (13th March 2000)*. Available at: http://www.parliament.the-stationery-office.co.uk/pa/cm199900/cmhansrd/vo000313/text/00313w15.htm.

Harris, C. A., Renfrew, M. J. and Woolridge, M. W. (2001) Assessing the risks of pesticide residues to consumers: recent and future developments. *Food Additives and Contaminants*, **18** (12): 1124-1129.

Harrison, C. and Harrison, T. (2003) *BRAME & Food Standards Agency*. Available at: http://www.brame.org/retailers0.html.

Health and Safety Executive (1978) *Health and Safety: Agriculture 1976*. HMSO. London.

Health and Safety Executive (1979) *Health and Safety: Agriculture 1977*. HMSO. London.

Health and Safety Executive (2007) *Pesticides Bluebook - Part A: The UK regulation of pesticides*. Available at: http://www.hse.gov.uk/pesticides/bluebook/parta.htm.

Health and Safety Executive (2008) *Pesticides Safety Directorate (PSD) transfers to HSE*. Available at: http://www.hse.gov.uk/news/2008/psd.htm.

Health Protection Agency (2009) *Mobile Telephony and Health Protection Advice*. Available at:

http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733769169.

Hempel, C. G. (1965) Science and Human Values. In: *Aspects of Scientific Explanation and other Essays in the Philosophy of Science*. The Free Press, New York**:** 81-96.

Hencke, D. (2003) *Minister defiant over controversial appointment*. The Guardian. (09/07/2003). Available at: http://www.guardian.co.uk/politics/2003/jul/09/uk.greenpolitics2

Henschler, D., Bolt, H. M., Jonker, D., Pieters, M. N. and Groten, J. P. (1996) Experimental Designs and Risk Assessment in Combination Toxicology: Panel Discussion. *Food and Chemical Toxicology*, **34**: 1183-1185.

Hilgartner, S. (2000) *Science on Stage: Expert Advice as Public Drama*. Stanford University Press, Stanford, CA.

HMSO (1952) *Agriculture (Poisonous Substances) Act*. [30th October 1952].

HMSO (1985) *Food and Environmental Protection Act 1985*. [16th July 1985].

HMSO (1986) *The Control of Pesticide Regulations 1986*. (S.I. 1510).

Hoffman, K. (2003) Permitting Poison: Public Participation, the Criteria for Action, and the Environmental Justice in the Case of Dioxin. In: (Ed. Casper, M. J.) *Synthetic Planet: Chemical Politics and the Hazards of Modern Life*. Routledge, New York.

Hoffmann-Reim, H. and Wynne, B. (2002) In risk assessment, one has to admit ignorance. *Nature*, **416**: 123.

Hough, P. (1998) *The Global Politics of Pesticides: Forging Consensus from Conflicting Interests*. Earthscan, London.

House of Commons Agriculture Select Committee (1987) *Effects of pesticides on human health*. Second special report: Volume 1, report and proceedings of the committee. HMSO. London.

House of Lords Select Committee on Science and Technology (2000) *Science and Society*. 3rd Report. HMSO. London.

IPCS (1990) *Environmental Health Criteria 104.* Principles for the toxicological assessment of pesticide residues in food. World Health Organisation, International Programme on Chemical Safety. Geneva. Available at: http://www.inchem.org/documents/ehc/ehc/ehc104.htm

IPCS (1999) *Environmental Health Criteria 210*. Principles for the Assessment of Risks to Human Health from Exposure to Chemicals. World Health Organisation, International Programme on Chemical Safety. Geneva. Available at:

http://www.inchem.org/documents/ehc/ehc/ehc210.htm

IPCS (2001) *Integrated Risk Assessment*. WHO/IPCS/IRA/01/12. WHO. Geneva. Available at:
http://www.who.int/ipcs/publications/new_issues/ira/en/index.html

Irwin, A. (1995) *Citizen Science: A study of people, expertise and sustainable development*. Routledge, London.

Irwin, A. (2006) The Politics of Talk: Coming to Terms with the 'New' Scientific Governance. *Social Studies of Science*, **36** (2): 299-320.

Irwin, A., Rothstein, H., Yearley, S. and McCarthy, E. (1997) Regulatory Science - Towards a Sociological Framework. *Futures*, **29** (1): 17-31.

James, P. (1997) *Food Standards Agency: an interim proposal by Professor Philip James*. 30 April 1997. London.

Jamieson, D. (1992) Ethics, public policy, and global warming. *Science, Technology & Human Values*, **17** (2): 139-153.

Jamieson, D. (1995) Scientific uncertainty and the political process. *Annals of the American Academy of Political and Social Science*, **545**: 35-43.

Jasanoff, S. (1986) *Risk Management and Political Culture: A Comparative Study of Science in the Policy Context*. Russell Sage Foundation, New York.

Jasanoff, S. (1987) Contested Boundaries in Policy-Relevant Science. *Social Studies of Science*, **17** (2): 195-230.

Jasanoff, S. (1990) *The fifth branch: Science advisors as policy makers*. Harvard University Press, Cambridge, MA.

Jasanoff, S. (1991) Acceptable Evidence in a Pluralistic Society. In: (Eds. Mayo, D. G. and Hollander, R. D.) *Acceptable Evidence: Science and Values in Risk Management*. Oxford University Press, New York**:** 29-47.

Jasanoff, S. (1996) The dilemma of environmental democracy. *Issues in Science and Technology*, **13** (1): 63-70.

Jasanoff, S. (1997a) Civilization and madness: the great BSE scare of 1996. *Public Understanding of Science*, **6**: 221-232.

Jasanoff, S. (1997b) NGOs and the environment: from knowledge to action. *Third World Quarterly*, **18** (3): 579-594.

Jasanoff, S. (2000) Technological Risk and Cultures of Rationality. In: (Ed. National Research Council) *Incorporating Science, Economics, and Sociology in Developing Sanitary and Phytosanitary Standards in International Trade*. National Academy Press, Washington, DC**:** 65-84.

Jasanoff, S. (2003) Breaking the waves in science studies. *Social Studies of Science*, **33**: 389-400.

Jasanoff, S., Ed. (2004) *States of Knowledge: The co-production of science and social order*. New York, Routledge.

Jensen, K. K. and Sandøe, P. (2002) Food Safety and Ethics: The interplay between science and values. *Journal of Agricultural and Environmental Ethics*, **15**: 245-253.

Kinchy, A. J. and Kleinman, D. L. (2003) Discursive and Organizational Orthodoxy on the Borders of Ecology and Politics. *Social Studies of Science*, **33** (6): 869-896.

Kloting, I., Nitschke, C. and van den Brandt, J. (2003) Impact of genetic profiles on experimental studies: outbred versus wild rats. *Toxicology and Applied Pharmacology*, **189** (1): 68-71.

Knorr-Cetina, K. D. (1981) *The Manufacture of Knowledge: An Essay on the Constructivist and Contextual Nature of Science*. Pergamon Press, Oxford.

Koenig, T. (2007) *Frame Analysis*. Available at:
http://www.ccsr.ac.uk/methods/publications/frameanalysis/.

Kortenkamp, A. (2002) *Consultation on the draft report of the Working Group on the Risk Assessment of Pesticides and Veterinary Medicines - Written Comments.* Sent to: Keith Butler (FSA), 25/03/2002.

Kraus, N., Malmfors, T. and Slovic, P. (1992) Intuitive Toxicology - Expert and Lay Judgements of Chemical Risks. *Risk Analysis*, **12** (2): 215-232.

Krimsky, S. (2005) The Weight of Scientific Evidence in Policy and Law. *American Journal of Public Health*, **95** (S1): 129-136.

Lane, M. B. and Morrison, T. H. (2006) Public interest or private agenda? A mediation on the role of NGOs in environmental policy and management in Australia. *Journal of Rural Studies*, **22**: 232-242.

Lawrie, C. A. (1998) Different dietary patterns in relation to age and the consequences of for intake of food chemicals. *Food Additives and Contaminants*, **15** (Supplement): 75-81.

Lean, G. and Emmett, S. (1996) *Pesticide danger warning was ignored for 45 years.* The Independent, London. 13th October 1996.

Levidow, L. (2003) Precautionary risk assessment of Bt maize: what uncertainties? *Journal of Invertebrate Pathology*, **83**: 113-117.

Lilleker, D. G. (2003) Doing Politics. Interviewing the Political Elite: Navigating a Potential Minefield. *Politics*, **23** (3): 207-214.

Lydy, M., Belden, J., Wheelock, C., Hammock, B. and Denton, D. (2004) Challenges in Regulating Pesticide Mixtures. *Ecology and Society*, **9** (6): 1 [online].

MAF130/61 *Ministry of Agriculture and Fisheries and Ministry of Agriculture, Fisheries and Food: Infestation Control Divisions: Registered Files, Infestation (I Series). (1950-1953)*. National Archives, London.

MAF 98/484 *Advisory Committee on Toxic Chemicals in Agriculture and Food Storage: meetings and reports (1954-1956)*. National Archives, London.

MAF 130/61 *Ministry of Agriculture and Fisheries and Ministry of Agriculture, Fisheries and Food: Infestation Control Divisions: Registered Files, Infestation (I Series). (1950-1953)*. National Archives, London.

MAF 130/62 *Working Party on Precautionary Measures against Toxic Chemical used in Agriculture: Stage II, Effects on the Consumer; second report dealing with possible hazards run by consumer who eats food which has been treated, or exposed to, toxic chemicals, April1953; consideration of working party's recommendation; setting up and minutes of first meeting of the Interdepartmental Advisory Committee on Poisonous Substances used in Agriculture and Food Storage (1953-1956)*. National Archives, London.

MAF 256/316 *Steering Group on Food Surveillance: Working Party on Pesticide Residues; minutes and papers*. National Archives, London.

MAF 260/90 *Control of pesticide residues in food: use of chemicals in agriculture (1957-1960)*. National Archives, London.

MAF 260/216 (1961) *Food Standards Committee & Food Additives and Contaminants Sub-Committee (1961)*. National Archives, London.

MAF 371 *Ministry of Agriculture and Fisheries and Ministry of Agriculture, Fisheries and Food: Advisory Committee on the Crop Protection Products Approval Scheme and predecessor: Minutes and Papers (1942-1958)*. National Archives, London.

MAFF (1986) *Pesticides: Implementing Part III of the Food and Environmental Protection Act 1985. Consultative Document on Pesticide Residues*. October 1986. National Archives. London.

MAFF and HSE (1990) Report of the Working Party on Pesticide Residues: 1988-89. *The Pesticides Register*, **8**.

Marrs, T. C. and Ballantyne, B., Eds. (2004) *Pesticide Toxicology and International Regulation*. Current Toxicology Series. Chichester, John Wiley & Sons Ltd.

Marsh, D. and Rhodes, R., Eds. (1992) *Policy Networks in British Government*. Oxford, Oxford University Press.

Martin, B. and Richards, E. (1995) Scientific Knowledge, Controversy, and Public Decision Making. In: (Ed. Jasanoff, S.) *Handbook of Science and Technology Studies*. Sage Publications Ltd, London.

Marton, F. (1981) Phenomenography - describing conceptions of the world around us. *Instructional Science*, **10**: 177-200.

Mason, J. (1996) *Qualitative Researching*. Sage Publications, London.

Medicines and Healthcare products Regulatory Agency (2007) *Good Laboratory Practice*. Available at: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodLaboratoryPractice/index.htm.

Mellanby (1974) *Biologist*, **21**: 131.

Michaels, D. and Monforton, C. (2005) Manufacturing Uncertainty: Contested Science and the Protection of the Public's Health and Environment. *American Journal of Public Health*, **95** (S1): 39-48.

Millstone, E. (2007) Can food safety policy-making be both scientifically and democratically legitimated? If so, how? *Journal of Agricultural and Environmental Ethics*, **20**: 483-508.

Millstone, E., Lang, T., Naska, A., Eames, M., Barling, D., van Zwanenberg, P. and Trichopoulou, A. (2000) 'European Policy on Food

Safety': Comments and suggestions on the White Paper on Food Safety. *Trends in Food Science & Technology*, **11**: 458-466.

Millstone, E. and van Zwanenberg, P. (2002) The Evolution of Food Safety Policy-making Institutions in the UK, EU and Codex Alimentarius. *Social Policy & Administration*, **36** (6): 593-609.

Milne, A. (1993) The perils of green pessimism. *New Scientist*, **138** (1877): 34-37.

Ministry of Agriculture and Fisheries and Food (1997) *News Release (83/97)*.

Mohr, A. and Raman, S. (2009) *Capturing the Public or Evoking the Moral Codes of Science?* In: Science and Democracy Network (SDN) Annual Conference, Harvard Kennedy School of Government, Cambridge, MA.

Moser, V. C., Casey, M., Hamm, A., Carter, W. H. J., Simmons, J. E. and Gennings, C. (2005) Neurotoxicological and statistical analyses of a mixture of five organophosphorus pesticides using a ray design. *Toxicological Sciences*, **86** (1): 101-115.

Mukerji, C. (1989) *A Fragile Power: Scientists and the State*. Princeton University Press, Princeton.

Mulkay, M. (1976) The Mediating Role of the Scientific Elite. Special Issue: Aspects of Sociology of Science: Papers from a Conference,

University of York, UK 16-18 September 1975. *Social Studies of Science*, **6** (3/4): 445-470.

Murphy, E. and Dingwall, R. (2001) 'The ethics of ethnography'. In: (Eds. Atkinson, P., Coffey, A., Delmont, S., Lofland, L. and Lofland, J.) *Handbook of Ethnography*. Sage Publications, London.

National Research Council (1993) *Pesticides in the Diets of Infants and Children*. National Academy Press, Washington, DC.

NC3Rs (2008) *About NC3Rs*. Available at: http://www.nc3rs.org.uk/landing.asp?id=2.

Nelkin, D. (1975) The Political Impact of Technical Expertise. *Social Studies of Science*, **5**: 35-54.

Nelkin, D., Ed. (1992) *Controversy: Politics of Technical Decisions*. London, Sage Publications Ltd.

O' Fallon, L. R. and Dearry, A. (2002) Community-Based Participatory Research as a Tool to Advance Environmental Health Sciences. *Environmental Health Perspectives*, **110** (S2): 155-159.

O' Fallon, L. R., Wolfe, G. M., Brown, D., Dearry, A. and Olden, K. (2003) Strategies for Setting a National Research Agenda That Is Responsive to Community Needs. *Environmental Health Perspectives*, **111** (16): 1855-1860.

Odendahl, T. and Shaw, A. M. (2002) Interviewing Elites. In: (Eds. Gubrium, J. F. and Holstein, J. A.) *Handbook of Interview Research: Context and Method*. Sage Publications Inc, Thousand Oaks, CA.**:** 299-316.

OECD (1982) *Good Laboratory Practice in the Testing of Chemicals.* Organisation of Economic Cooperation and Development, 75775, Cedex. Paris.

OECD (1993) *Guidelines for the Testing of Chemicals*. OECD, Paris.

Office for Official Publications of the European Communities (1991) *Council Directive of 15 July 1991 concerning the placing of plant protection products on the market. CONSLEG: 1991L1414 - 01/01/2004*. (91/414/EEC).

Office of Science and Technology (1997) *The use of scientific advice in policy making*. (The May Guidelines). Department of Trade and Industry.

Ontario College of Family Physicians (2004) *Pesticides Literature Review*. Environment and Health. Available at: http://www.ocfp.on.ca/english/ocfp/communications/publications/default.asp?s=1#EnvironmentHealth

Oreskes, N. (2004) Science and public policy: what's proof got to do with it? *Environmental Science & Policy*, **7**: 369-383.

Pennycook, F. R., Diamand, E. M., Watterson, A. and Howard, C. V. (2004) Modelling the Dietary Pesticide Exposures of Young Children. *International Journal of Environment and Health*, **10**: 304-309.

Pesticide Action Network (1997) *Food fit for our children?* Available at: http://www.pan-uk.org/pestnews/Pn35/pn35p17.htm.

Pesticide Action Network (2002) *Pesticide Action Network Review 2002*. Available at: http://www.pan-uk.org/Publications/Reviews/AR2002.pdf.

Pesticide Action Network (2004) *People's Pesticide Exposure*. Poisons we are exposed to everyday without knowing it. Available at: http://www.pan-uk.org/Publications/Briefing/PeoplesPesticideExposures.pdf

Pesticide Action Network (2005a) *Pesticide Action Network - UK*. Available at: http://www.pan-uk.org/default.htm.

Pesticide Action Network (2005b) *Royal Commission slams UK risk assessment*. Available at: http://www.pan-uk.org/pestnews/Issue/pn70/pn70p8.htm.

Pesticide Residues Committee (2002) *Pesticide Residues Monitoring Report*. Second Quarter Results 2002 (April -June). PSD. London. Available at: http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PRC/PRC_2002_Q2_report.pdf

Pesticide Residues Committee (2008) *Maximum Residue Levels (MRL)*. Available at: http://www.pesticides.gov.uk/prc.asp?id=956.

Pesticide Residues Committee (2009) *The Role of the PRC*. Available at: http://www.pesticides.gov.uk/prc.asp?id=824.

Pesticide Safety Directorate (2003a) *Consultation on the Introduction of No-Spray Buffer Zones Around Residential Properties*. Available at: http://www.pesticides.gov.uk/publications.asp?id=431.

Pesticide Safety Directorate (2003b) *Dietary Risk Assessment for Multiple Pesticides in Combination*. Available at: http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/ACP/ACP_Dietary_risk_assessment_paper_v2.pdf.

Pesticide Safety Directorate (2005) *PSD and ACP approach to assessing the mammalian toxicity (and consumer/operator risk assessment) of two or more compounds in a pesticide product (formulation).* Available at: http://www.pesticides.gov.uk/uploadedfiles/web_assets/psd/combinedtoxicity20050408.pdf.

Pesticide Safety Directorate (2006b) *EC Maximum Residue Level (MRL)s Explained*. Available at: http://www.pesticides.gov.uk/food_safety.asp?id=543.

Pesticide Safety Directorate (2008) *A Glossary of PSD Terms*. Available at: http://www.pesticides.gov.uk/appendices.asp?id=744.

Petts, J. and Leach, B. (2000) *Evaluating Methods for Public Participation: Literature Review*. R & D Technical Report: E135. Environment Agency. Birmingham.

Phillips, N. A. (2000) *The BSE Inquiry: The Report*. The Inquiry into BSE and variant CJD in the United Kingdom. HMSO. London. Available at: http://www.bseinquiry.gov.uk/report/volume7/chapteg2.htm#416289

Phthalate Information Centre (2005) *What are Phthalates?* Available at: http://www.phthalates.org/whatare/.

Platt, B. S. (1955) Human Nutrition and the Sophistication of Foods and Feeding Habits. *British Medical Journal*, **1** (4907): 179-185.

Poppy, G. (2000) GM crops: environmental risks and non-target effects. *Trends in Plant Science*, **5** (1): 4-6.

Powerwatch (2009) *A basic guide to EMFs*. Available at: http://www.powerwatch.org.uk/.

Press Association (2003) *Defra accused of cronyism*. The Guardian (08/07/2003). Available at: http://www.guardian.co.uk/politics/2003/jul/08/Whitehall.uk

Prior, L. (2008) Repositioning Documents in Social Research. *Sociology*, **42** (5): 821-836.

Rajapakse, N., Silva, E. and Kortenkamp, A. (2002) Combining Xenoestrogens at Levels below Individual No-Observed-Effect Concentrations Dramatically Enhances Steroid Hormone Action. *Environmental Health Perspectives*, **110** (9): 917-921.

Ravetz, J. R. (2002) Food Safety, Quality and Ethics - A Post Normal Perspective. *Journal of Agricultural and Environmental Ethics*, **15**: 255-265.

Renn, O. (2003) Hormesis and risk communication. *Human & Experimental Toxicology*, **22** (1): 3-24.

Risk Assessment and Toxicology Steering Committee (1999) *Risk Assessment Approaches Used by UK Government for Evaluating Human Health Effects of Chemicals*. Research Councils Initiative on Risk Assessment and Toxicology, London.

Risk Assessment and Toxicology Steering Committee (1999 b) *Physiologically-based pharmacokinetic modelling: A potential tool for use in risk assessment*. Report of a workshop organised by the Risk Assessment and Toxicology Steering Committee. Institute for Environment and Health. Leicester.

Rothstein, H. (2003) *Precautionary Bans or Sacrificial Lambs?* Participative Risk Regulation and the Reform of the UK Food Safety Regime. Centre for Analysis of Risk and Regulation. Available at: http://eprints.lse.ac.uk/352/1/CARR-Disspaper15.pdf

Rothstein, H., Irwin, A., Yearley, S. and McCarthy, E. (1999) Regulatory Science, Europeanization, and the Control of Agrochemicals. *Science, Technology & Human Values*, **24** (2): 241-264.

Royal Commission on Environmental Pollution (1979) *Agriculture and Pollution*. 7th Report. HMSO. London.

Royal Commission on Environmental Pollution (1998) *Setting Environmental Standards*. 21st Report. HMSO. London. Available at: http://www.rcep.org.uk

Royal Commission on Environmental Pollution (2003) *Chemicals in Products: Safeguarding the Environment and Human Health*. 24th Report. HMSO. London. Available at: http://www.rcep.org.uk

Royal Commission on Environmental Pollution (2005) *Crop Spraying and the Health of Residents and Bystanders*. 25th Report. HMSO. London. Available at: http://www.rcep.org.uk

Royal Commission on Environmental Pollution (2006) *Royal Commission on Environmental Pollution (RCEP) Response to the Commentary of the Advisory Committee on Pesticides on the RCEP's Report on Crop Spraying and the Health of Residents and Bystanders*. Available at: http://www.rcep.org.uk/pesticides/ResponsetoACPResponse.pdf.

Royal Courts of Justice (2009) *The Corby Group Litigation*. Case No: HT-09-63. High Court of Justice, Queen's Bench Division, Technology and Construction Court. Available at: http://www.judiciary.gov.uk/docs/judgments_guidance/corby-group-corby-district-council.pdf

Russell, P. E. (2005) Centenary Review: A century of fungicide evolution. *Journal of Agricultural Science*, **143**: 11-25.

Russell, P. E. (2006) The development of commercial disease control. *Plant Pathology*, **55**: 585-594.

Salter, L. (1988) *Mandated Science: Science and Scientists in the Making of Standards*. Kluwer, Dordrecht.

Santillo, D., Johnston, P. and Stringer, R. (2000) Management of chemical exposure: the limitations of a risk-based approach. *International Journal of Risk Assessment and Management*, **1** (1/2): 160-180.

Sarewitz, D. (2004) How science makes environmental controversies worse. *Environmental Science & Policy*, **7**: 385-403.

Sarewitz, D., Foladori, G., Invernizzi, N. and Garfinkel, M. S. (2004) Science policy in its social context. *Philosophy Today*, **48** (5): 67-83.

Sarkissian, W., Cook, A. and Walish, K. (1997) *Community Participation in Practice: A Practical Guide.* Community Participation in Practice: A

Practical Guide. Institute for Science Technology Policy. Murdoch University. Western Australia.

Scholze, M. and Kortenkamp, A. (2007) Statistical Power Considerations Show the Endocrine Disruptor Low-Dose Issue in a New Light. *Environmental Health Perspectives*, **115** (S1): 84-90.

Schottenfeld, R. (1987) "Workers with Multiple Chemical Sensitivities: A Psychiatric Approach to Diagnosis and Treatment". In: (Ed. Cullen, M.) *Workers with Multiple Chemical Sensitivities*. Hanley and Belfus, Philadelphia.

Science and Technology Select Committee (2000) *Science and Society*. Third Report - HL 38. HMSO. London. Available at: http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/38/3801.htm

SEAC (2009) *Code of Practice for the Spongiform Encephalopathy Advisory Committee (SEAC)*. Available at: http://www.seac.gov.uk/papers/paper87-5.pdf.

Shackley, S. and Wynne, B. (1995) Global climate change: The mutual construction of an emergent science-policy domain. *Science and Public Policy*, **22** (4): 218-230.

Shackley, S. and Wynne, B. (1996) Representing Uncertainty in Global Climate Change Science and Policy: Boundary-Ordering Devices and Authority. *Science, Technology & Human Values*, **21** (3): 275-302.

Shackley, S., Young, P., Parkinson, S. and Wynne, B. (1998) Uncertainty, Complexity and Concepts of Good Science in Climate Change Modelling: Are GCMs the Best Tools? *Climatic Change*, **38**: 159-205.

Shapin, S. (1992) "Discipline and Bounding: The history and sociology of science as seen through the externalism-internalism debate". *History of Science*, **30** (90): 333-369.

Sheehan, D. M. (2006) No-threshold dose–response curves for nongenotoxic chemicals: Findings and applications for risk assessment. *Environmental Research*, **100**: 93-99.

Shore, A. (2003) Indoor Air Pollution: Environmental Inequality Inside. In: (Ed. Casper, M. J.) *Synthetic Planet: Chemical Politics and the Hazards of Modern Life*. Routledge, London.

Shrader-Frechette, K. (1991) *Risk and Rationality: Philosophical foundations for populist reforms*. University of California Press, Berkeley.

Silver, M. L. and Pollock, G. H. (1948) Role of Carbon Dioxide and of the Hindbrain in Agene-Induced Canine Epilepsy. *American Journal of Physiology*, **154**: 439-442.

Silverman, D. (2001) *Doing Qualitative Research: A Practical Handbook*. Sage Publications, London.

Solecki, R., Davies, L., Dellarco, V., Dewhurst, I., van Raaij, M. and Tritscher, A. (2005) Guidance on setting of acute reference dose (ARfD) for pesticides. *Food and Chemical Toxicology*, **43**: 1569-1593.

Stacy, J. (1991) 'Can there be a feminist ethnography?' In: (Eds. Gluck, S. and Patai, D.) *Women's words: The Feminist Practice of Oral History*. Routledge, New York.

Star, S. L. and Griesemer, J. R. (1989) Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39'. *Social Studies of Science*, **19** (3): 387-420.

Steinmetz, R., Mitchner, N. A., Grant, A., Allen, D. A., Bigsby, R. M. and Nira, B. J. (1998) The Xenoestrogen Bisphenol A Induces Growth, Differentiation, and c-*fos* Gene Expression in the Female Reproductive Tract. *Endocrinology*, **139** (6): 2741-2747.

Stern, P. C. and Fineburg, H. V. (1996) *Understanding Risk: Informing Decisions in a Democratic Society.* Understanding Risk: Informing Decisions in a Democratic Society. National Academy Press. Washington DC.

Stewart, D. W. (1984) *Secondary Research. Information Sources and Methods.* Sage Publications, California.

The Cabinet Office (1999) *Modernising Government*. White Paper. TSO. London. Available at: http://www.archive.official-documents.co.uk/document/cm43/4310/4310.htm

The Cabinet Office (2001) *Be the Change: Peer Review Report of the Cabinet Office Role in Modernising Government*. Modernising Government. Available at: http://archive.cabinetoffice.gov.uk/moderngov/peerreview/Peer%20review.pdf

The Strategy Unit (2002) *Risk: Improving government's capability to handle risk and uncertainty*. Summary Report. The Cabinet Office. London. Available at: http://www.strategy.gov.uk/downloads/su/risk/report/downloads/su-risk-summary.pdf

Timbrell, J. (2002) *Introduction to Toxicology*. Taylor and Francis, London.

Tizard, H. T. (1951) *Fourth Annual Report of the Advisory Council on Scientific Policy (1949-1950)*. Cmd 8299. HMSO. London.

United Nations (1985) *Guidelines for Consumer Protection*. A/RES/39/248. Available at: http://www.un.org/documents/ga/res/39/a39r248.htm

van der Sluijs, J., van Eijnhoven, J. C. M., Shackley, S. and Wynne, B. (1998) Anchoring Devices in Science Policy: The Case of Consensus around Climate Sensitivity. *Social Studies of Science*, **28** (2): 291-323.

van Veen, M. P., van Engelen, J. G. M. and van Raaij, M. T. M. (2001) Crossing the river stone by stone: Approaches for residential risk assessment for consumers. *Annals of Occupational Hygiene*, **45** (S1): 107-118.

van Zorge, J. A. (1996) Exposure to Mixtures of Chemical Substances: is there a Need for Regulation? *Food and Chemical Toxicology*, **34**: 1033-1036.

van Zwanenberg, P. (1996) *Science, Pesticide Policy and Public Health: Ethylene Bisdithiocarbamate Regulation in the UK and USA.* SPRU, University of Sussex. Sussex.

van Zwanenberg, P. and Millstone, E. (2000) Beyond Skeptical Relativism: Evaluating the Social Constructions of Expert Risk Assessments. *Science, Technology & Human Values*, **25** (3): 259-282.

van Zwanenberg, P. and Millstone, E. (2005) *BSE: Risk, Science and Governance*. Oxford University Press, Oxford.

Vermeire, T. G., Baars, A. J., Bessems, J. G. M., Blaauboer, B. J., Slob, W. and Muller, J. J. A. (2007) Toxicity Testing for Human Health Risk Assessment. In: (Eds. van Leeuwen, C. J. and Vermeire, T. G.) *Risk Assessment of Chemicals: An Introduction*. Springer, The Netherlands.

Vidair, C. A. (2004) Age dependence of organophosphate and carbamate neurotoxicity in the postnatal rat: extrapolation to the human. *Toxicology and Applied Pharmacology*, **196**: 287 - 302.

Vogel, D. (1986) *National Style of Regulation*. Cornell University Press, New York.

Ware, G. and Whitacre, D. (2004) *The Pesticide Book*. Meister Media Worldwide, Willoughby, OH.

Watterson, A. (1990) UK pesticide health and safety regulatory policy: past achievements and limitations. *Journal of Public Health Medicine*, **12** (3/4): 181-185.

Weinberg, A. (1972) Science and Trans-Science. *Minerva*, **10** (2): 209-222.

Weinhold, B. (2003) Body of Evidence. *Environmental Health Perspectives*, **111** (7): 394-398.

Weisenburger, D. D. (1993) Human health effects of agrichemical use. *Human Pathology*, **26** (6): 571-6.

Wharfe, J., Tinsley, D. and Crane, M. (2004) Managing Complex Mixtures of Chemicals - a Forward Look from the Regulator's Perspective. *Ecotoxicology*, **13**: 485-492.

Whitford, F., Ed. (2002) *The Complete Book of Pesticide Management: Science, Regulation, Stewardship and Communication*. New York, John Wiley & Sons.

Williams, G. and Popay, J. (2001) Lay health knowledge and the concept of the lifeworld. In: (Ed. Scambler, G.) *Habermas, Critical Theory and Health*. Routledge, London.

Wilsdon, J., Wynne, B. and Stilgoe, J. (2005) The Public Value of Science: Or how to ensure that science really matters. Demos, London.

Wind, S., Van Sickle, D. and Wright, A. L. (2004) Health, place and childhood asthma in Southwest Alaska. *Social Science & Medicine*, **58**: 75-88.

Women's Environmental Network (2004) *Ending the cosmetics cover up*. Available at: http://www.wen.org.uk/cosmetics/index.htm.

Worcester, R. M. (2001) *Science and Society: What scientists and the public can learn from each other*. Available at: http://www.ipsos-mori.com/publications/rmw/cambridge.pdf.

World Health Organisation, International Labour Organization and United Nations Environment Programme (2003) *Toxicogenomics and the Risk Assessment of Chemicals for the Protection of Human Health*. IPCS/Toxicogenomics/03/1. International Programme on Chemical Safety (IPCS). Berlin.

WWF-UK (2004) *Contamination: the next generation. Results of the family chemical contamination survey*. In conjunction with: The Cooperative Bank. Godalming. Available at: http://www.wwf.org.uk/filelibrary/pdf/family_biomonitoring.pdf

Wynne, B. (1982) *Rationality or Ritual? Nuclear Decision-making and the Windscale Inquiry*. British Society for the History of Science Monographs, Chalfont St Giles.

Wynne, B. (1992) Uncertainty and environmental learning: Reconceiving science in the preventative paradigm. *Global Environmental Change*, **2**: 111-127.

Wynne, B. (1996) Misunderstood misunderstandings: social identities and public uptake of science. In: (Eds. Irwin, A. and Wynne, B.) *Misunderstanding science? The public reconstruction of science and technology*. Cambridge University Press, Cambridge.

Wynne, B. (1998) May the sheep safely graze? In: (Ed. Lash, S., Szersynski, B., Wynne, B) *Risk, Environment and Modernity: Towards a New Ecology*. Sage Publications, London.

Wynne, B. and Mayer, S. (1993) How science fails the environment. *New Scientist*, **138** (1876): 32-35.

Yearley, S. (1991) Greens and science: a doomed affair? *New Scientist*, **1777**: 37-40.

Yearley, S. (1992 -a) Green Ambivalence about Science: Legal-Rational Authority and the Scientific Legitimation of a Social Movement. *The British Journal of Sociology*, **43** (4): 511-532.

Yearley, S. (1992 -b) Skills, Deals and Impartiality: The Sale of Environmental Consultancy Skills and Public Perceptions of Scientific Neutrality. *Social Studies of Science*, **22** (3): 435-453.

Yearley, S. (1996) Nature's advocates: putting science to work in environmental organisations. In: (Eds. Irwin, A. and Wynne, B.) *Misunderstanding Science? The Public Reconstruction of Science and Technology*. Cambridge University Press, Cambridge.

Appendix

Abbreviations

ABIM	Association of British Insecticide Manufacturers
ACAS	Agricultural Chemicals Approval Scheme
ACP	The Advisory Committee on Pesticides
ADI	Acceptable Daily Intake
AOEL	Acceptable Operator Exposure Level
ARfD	Acute Reference Dose
BCPC	British Crop Protection Council
BMA	British Medical Association
BSE	Bovine Spongiform Encephalopathy
CFS	Chronic Fatigue Syndrome
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COM	Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
COPR	UK Control of Pesticides Regulations
COT	The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
CPPAS	Crop Protection Products Approval Scheme
CSL	Central Science Laboratories

DEFRA	Department for Environment, Food and Rural Affairs
DNT	Developmental Neurotoxicity
EC	European Commission
ECVAM	European Centre for the Validation of Alternative Methods
EFSA	European Food Safety Authority
EU	European Union
FACS	Food Additives and Contaminants Sub-Committee
FAO	Food and Agriculture Organisation
FEPA	UK Food and Environmental Protection Act
FoE	Friends of the Earth
FQPA	United States Food Quality Protection Act
FSA	Food Standards Agency
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
HMSO	Her Majesty's Stationary Office
HSE	Health and Safety Executive
IDS	The Inter-Departmental Secretariat
IPCS	International Programme on Chemical Safety

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	Lowest Observed Adverse Effect Level
MAF	Ministry of Agriculture and Food
MAFF	Ministry of Agriculture, Fisheries and Food
MCSS	Multiple Chemical Sensitivity Syndrome
MRL	Maximum Residue Limit
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
NEL	No Effect Level
NOAEL	No Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
PAN	Pesticide Action Network
PEX	Pesticide Exposure Network
PIAP	Pesticide Incident Appraisal Panel
PPPD	Plant Protection Products Directive
PPPR	Plant Protection Product Regulation
PRC	Pesticide Residues Committee
PSD	The Pesticide Safety Directorate
PSPS	Pesticide Safety Precaution Scheme

QSAR	Quantitative Structure-Activity Relationships
RCEP	Royal Commission on Environmental Pollution
SCFA	Standing Committee on Food Chain and Animal Health
SEAC	Spongiform Encephalopathy Advisory Committee
SCP	Scientific Committee on Plants
STS	Science and Technology Studies
UN	United Nations
VMD	Veterinary Medicines Directorate
VUT	Working Group on Variability and Uncertainty in Toxicology
WHO	World Health Organisation
WiGRAMP	Working Group On Risk Assessment Of Mixtures Of Pesticides
WPPR	Working Party on Pesticide Residues

Interview Schedule

Interviewee Code Letter	Interview Date	Organisation/Role
A	3rd July 2007	COT Working Group Member
B	8th July 2008	FSA Science Policy Advisor
C	5th September 2007	Soil Association Staff Member
D	3rd October 2007	Senior FSA Toxicologist
E	17th October 2007	Former RCEP Chairman
F	23rd May 2007	COT Working Group Member
G	19th September 2007	Former PAN Staff Member
H	8th August 2007	ACP Member
I	30th July 2007	Former ACP Member
J	11th June 2007	COT Working Group Member
K	12th July 2007	Senior PSD Toxicologist
L	24th August 2007	ACP Member
M	17th September 2007	CSL Scientist
N	10th July 2007	ACP Member

Interviewee Code Letter	Interview Date	Organisation / Role
O	9th October 2007	ACP Member
P	26th July 2007	Academic Mixtures Toxicologist
Q	31st July 2007	PAN Staff Member
R	21st May 2008	Regulatory Affairs Manager for Multinational Chemical Company
S	16th May 2007	COT Working Group Member
T	13th June 2007	COT Working Group Member
U	4th June 2007	COT Working Group Member
V	21st May 2008	BCPC Representative
W	28th August 2007	Academic Computational Toxicologist
X	7th August 2007	ACP Member
Y	31st July 2007	PAN Staff Member

Sample Interview Questions

Initial Discussion:

Gather information about their professional background and professional commitments relating to the assessment and management of pesticides.

- Compared to other areas of chemical food risk assessment, do you think the issue of pesticide residues in food is important?
- What do they consider to be their main concerns regarding pesticide residues in food?

Main Questions:

VUT Report

I want to talk a little about the report on Variability and Uncertainty of Chemicals in food and consumer products. The recent VUT report stated there was a need for guidelines in the standardised reporting of toxicological studies and systematic reviews:

- Do you think that current guidelines are acceptable?
- What benefits/drawbacks do you see from standardising guidelines?
- What impact do you think this will have on the use of animals in toxicity testing?
- How is evidence such as scientific studies selected for inclusion when drafting reports or giving advice?
- What selection criteria do you use and how do you reject or otherwise weigh evidence?
- How do ensure that this process is consistent?

- Can you think of occasions when there has been disagreement over the inclusion or rejection of evidence – what typically occurs in this situation?
- In general, how much data do you need to make a decision?
- What happens when there is insufficient data to reach a conclusion/decision?
- What do you think will be the benefits/drawbacks of a central European registration system and the introduction of standard evidence documents?

Methods

Many articles and reports that I have read discuss the possibility of using new methods in the risk assessment of chemicals, often highlighting their advantages over older methods.

- Do you consider new methods to be as reliable as older methods?
- In your opinion, how do you think that difficulties relating to new methods can be overcome?
- Do you think that methods such as probabilistic dose-response modelling, QSARs, PBPK modelling, meta-analytical techniques can be better used to address gaps in the data or aid in the interpretation of data?
- Why have these techniques not been used to a greater extent in previous research?
- How can we better use existing/older data?
- How should we deal with studies that give conflicting/contradictory results?
- What value do you place on the use of human data?

- How can we better use epidemiological data?
- Do you think advisory bodies/regulators should be more open towards accepting new methodology?

Uncertainty

The ACP acknowledges that there is inherent uncertainty in the risk assessment of pesticides which must be accounted for when deciding how to manage risks; a point that is also made in the recent VUT report which states that uncertainty and variability should be identified and characterised.

- What do you see as the main sources of uncertainty in the risk assessment process?
- What methods do you think could or should be used to identify and characterise such uncertainty?
- What do think would be added to the process of risk assessment by identifying uncertainty?
- Do you think it is important to resolve uncertainty?
- How could this be achieved?

Uncertainty Factors

Much literature, including the recent VUT report, raises concerns regarding the adequacy of uncertainty factors in protecting susceptible subgroups and for extrapolating from adults to children:

- In a recent ATLA article, FRAME state that they believe uncertainty factors to be arbitrary: Do you agree with this opinion that they should be chemical specific?

- Some literature has suggested that an additional safety factor be used in relation to infants and children. Do you think current arrangements are adequate to ensure an acceptable level of safety for the whole population?
- If you could, would you alter the current use of uncertainty factors? If yes, how and why?

Expertise and Wider Inclusion

- What role do you see experts/scientists as having in the risk assessment or risk management process?
- Where expert judgement is used how can we ensure that it is reliable, valid and transparent?
- Are these relevant qualities?
- In what way does the use of expert judgement affect the RA and RM process?
- Who counts as an expert in this sense?

The FSA was set up with the goal of wider inclusion and the aim of making decision-making more transparent:

- Why do you think they placed emphasis on inclusion and transparency?
- Do you think this goal has been achieved?
- What, if any, effect on advisory discussions does the inclusion of the public or campaign groups have on the discussions and final decisions/reports?
- What benefits/drawbacks occur as a result of wider inclusion?

- Are there any groups or representatives that are not currently included in the discussion surrounding the risk assessment and management of pesticides that you think should be there?
- What else in your opinion needs/could be done to meet the FSA's goals?

Residue Limits

As you are aware, it was not until 1985 the Food and Environmental Protection Act that many aspects relating to pesticide use and exposure, including maximum residue limits in food, became legally enforceable within England:

- In your opinion, do you think it is necessary to have legally enforceable limits?
- What do you think are/were the benefits of changing to limits that are legally enforced?
- How well do you think the older system of voluntary notification of pesticides worked in respect to consumer safety?
- What do you consider to be the benefits and drawbacks of a statutory system?
- What do you see as the benefits and drawbacks of being harmonised with Europe in terms of the risk assessment process and in terms of setting limits such as the MRL?
- Some have argued that the harmonisation with Europe, including the setting up of National and European advisory bodies has increased the bureaucracy in the assessment and regulation of pesticides:
- What impact do you think European integration has had on the process?

Research from the 90s onwards has suggested that there is variability in the amount of pesticide residues found in products with the result that there are occasional, random instances of high residue levels in individual crop units. However, the UK's assessment of the issue was that even the highest residues were unlikely to lead to adverse health effects:

- Do you agree with this statement? Why?
- How do you suggest that this variability is dealt with?
- Do we need to alter monitoring and sampling techniques?
- Where do you think the responsibility lies for this?
- Do you think the public need to be better informed about pesticides and methods to lower their exposure?

Mixtures

There is a recognised problem regarding this issue in relation to the effects of exposure to mixtures of pesticides, especially those with a common mechanism of action or those that may cause synergistic effects. Some research also suggests that interactions at low-levels may cause toxicological effects. Despite a growing concern, the WiGRAMP reported that the risks posed by exposure to mixtures is likely to be small:

- Do you agree with this statement and why? (If in WiGRAMP) Were there many differences of opinion within the working group regarding this statement?
- What do you see as the main concerns in relation to the exposure to chemical mixtures?
- Do you think that certain sub-groups are more at risk than others? Which ones?

- Do you think current risk assessment methods adequately deal with this issue?
- If not why not, how can they be adapted? Is this feasible?

The literature in this area often highlights that we are exposed to pesticides from a variety of sources, leading many to suggest that that we need to adopt a cumulative approach as is advocated in the US:

- Do you agree with this? Why?
- What do you think we (the UK and Europe) can learn from the US on this issue?
- Why do you think that the UK differs to the US on this issue?

Vulnerable Sub-Groups

Much literature on this issue is concerned with potentially vulnerable sub-groups of the population such as infants, children and the elderly. I have noticed that this point is frequently raised as a concern by NGOs and campaign groups:

- How would you respond to the criticism made by such groups in relation this issue?

  The EU Scientific Committee for Food stated that it was not in a position to know whether all core tests relevant to risk assessment in infants and young children have been conducted for every pesticide in use with the EU:
- What do you consider to be the main obstacles to overcome this situation?
- Do you think the current system of assessment and monitoring is effective for all of the population?

- Are there changes that need to be made, or do we need to include a wider range of toxicological data such as teratogenic effects for pregnant women as suggested by Harris or look more closely at neurological effects?
- If so, at what level of assessment and management should changes be made?

There is some scientific literature, which is often used by campaign groups, that suggests that instances of poisoning or ill health as a result of exposure to pesticides may be more common than statistics suggest as at is unlikely to be diagnosed as pesticide related by healthcare professionals:

- In your opinion, do you think this is likely to be the case?
- What weight would you place on claims made that suggest ill health may result as a result of exposure to levels considered as safe e.g. at below the ADI?

Precautionary Principle

The ACP make the suggestion that the precautionary principle should be routinely applied in the regulation of new pesticides:

- What do you consider to be a precautionary approach?
- How safe is safe enough?
- What difficulties are faced in applying a precautionary approach to older substances that have been in use for many years?
- How do you think the introduction of directives such as the PPPR and REACH will affect pesticide registration and use?

There is an argument to be made (WHO & RCEP) that the only real solution to concerns regarding pesticide exposure is to reduce its use and find alternative means of pest control:

- Where do you stand on this issue?

- Finally, if you could change one aspect in the risk assessment and management of pesticide residues what would it be and why?

WiGRAMP Specific:

There were many comments submitted regarding the draft publication of the WiGRAMP report:

- Can you summarise what the main comments or concerns were?
- Do you think that the final draft adequately addressed the submitted comments?

NGO Specific:

- Can you tell me a little about your organisation's work in the area of pesticides:
- How do you conduct your research?
- Is it done in-house by who, what qualifications/expertise do they have?
- Is it peer reviewed? Is this important?
- Do they consider themselves to be scientists?
- What criteria do they use to select/reject material?
- Do they think that their selection process differs to that selected for regulatory/official purposes?

- On what grounds?
- As an NGO do they feel more or less constrained than other groups in what evidence they use?
- Who do they think is their audience and how do they think their work is received by those in the ‘scientific’ and ‘regulatory’ community?
- How does their organisation participate in the regulation of pesticides?
- What do they see themselves contributing to the discussion that is not available elsewhere?