Stakeholders' perceptions of genetically modified crops: the environmental risks, current regulatory approach & future management goals.

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To James Chew: a true scientist and much loved grandfather.

Whose bear hugs provided as much comfort now, through the trials and tribulations of my PhD, as they did when I was a child and had grazed my knee; and whose love of science and ability to understand first principles has truly inspired me to be a scientist.

Declaration of authorship

I, **Katherine Louise Johnson,** declare that this thesis entitled "**Stakeholders perceptions of genetically modified crops: the environmental risks, current regulatory approach and future management goals**" and all the work presented in it is my own. I confirm that:

- This work was done wholly or mainly while in candidature for a research degree at this University;
- Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- Where I have consulted the published work of others, this is always clearly attributed;
- Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- Where the thesis is based on work done by myself jointly with others I have made clear exactly what has been done by others and what I have contributed myself;
- None of this work has been published before submission;

Signed…

Date…

"All progress is precarious, and the solutions to one problem brings us face-to-face with another problem" Martin Luther King Jr.

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Abstract

Genetically modified crops have the capacity to bring great benefits to agriculture, but alongside these benefits there are numerous inherent risks. Before being approved for commercial cultivation or even experimental release, genetically modified crops are required to undergo stringent regulatory assessment to evaluate their potential to harm both human health and the environment. In Europe, despite having the most comprehensive regulatory assessment, genetically modified crops have gained significant negative press and public hostility. It seems the regulatory system instils little public confidence and is frequently criticised by a range of stakeholder groups.

This study considers the concerns of a range stakeholder groups in relation to the environmental risk associated with genetically modified crops, and the regulatory process governing their use. These groups include: farmers, governments and advisory bodies, industry, non-governmental organisations and scientists. By identifying the concerns held by the stakeholders, the extent to which current systems are addressing these concerns were evaluated. Comparisons were also drawn between groups, allowing areas of similarity and dissimilarities in their concerns to be highlighted. This could help explain the animosity between certain sections involved in the debate but also provide platforms of commonality. The stakeholder groups were also asked to identify management goals and assessment endpoints which addressed their concerns, and could be used to drive the current regulatory assessment. A combination of qualitative and quantitative methodological approaches were undertaken to achieve the aims of this study. Semi-

structured qualitative interviews were analysed using concept mapping techniques and content analysis. Quantitative descriptive statistics were then applied in order to identify key themes, as well as similarities and differences between stakeholder groups.

While this study uncovered numerous discussion points; four issues in particular have been presented as the key findings in the general discussion. The first two are concerns with the evaluation of the environmental implications of genetically modified crops. If environmental implications are to be properly evaluated, then the risks posed need to be considered within the context of the potential benefits, as well as those risks posed by conventional production methods. These are points raised throughout the study by all the stakeholder groups, who felt that the lack of contextualisation meant that risks were often amplified and as a result the potential benefits were often neglected. The third involved the roles of the scientific assessment of risk and societal concerns within the regulatory decision making process. Currently it is unclear how societal concerns are addressed within the regulatory procedure. This is a concern of all the stakeholder groups; who stipulated a need for a framework that clearly incorporates societal concerns and enables the assessments of risks to be placed back within this context. Finally familiarity and trust have important roles in the acceptance of regulatory decisions; however they place different requirements on the regulatory process, both sets of requirements need to be considered if acceptance of the regulatory decisions is to be improved. Currently the regulatory process takes on board the requirements made by those familiar with the process, the scientists and government groups, but not those made by the groups reliant on trust, the farmers and non-governmental organisations, thus alienating these groups.

By addressing these four key points, societal acceptance of the crops and also the regulatory process could be significantly improved. This not only has implications of genetically modified crops, but scientific innovations across the board. Much can be learnt from the societal furore which has engulfed genetically modified crops and their regulation in Europe. If we applied a similar approach to other areas of scientific research and innovation, for example stem cell research or nanotechnology, it is hoped that the mistakes made with genetically modified crops will not be revisited and societal acceptance will be more easily achieved.

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can then be consider in the applicants PMEM plan. Additional environment monitoring carried out under the responsibility of Member States can be integrated into PMEM plans as well. National Competent Authority might ask applicants to review its monitoring plan.

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Abbreviations and Acronyms

Abbreviation/ Acronyms	Full Word	Abbreviation/ Acronyms	Full Word
AB	Advisory Body	FMP	Fame Management Practices
ACRE	Advisory Committee on Releases to the Environment	FP	Food Production
AC	Already Commercialised	FSE	Farm Scale Evaluation
Adv	Advantages	Gen Uni	Genetic Uniformity
AEBC	Agricultural and Environmental Biotechnology Commission	GF	Gene Flow
Agri	Agriculture	GM	Genetic Modification
AR	Antibiotic Resistance	GMD	Genetic Modification Debate
Avail	Available	Gov	Government
B/d	Biodiversity	HH	Human Health
Bt	*Bacillus thuringenesis*	HM	Herbicide Management
C-b-C	Case-by-Case	HT	Herbicide Tolerant
CBP	Cartagena Biosafety Protocol	IC	Identification of Concerns
CCP	Comparisons to Current Practices	FMP	Fame Management Practices
Comm	Communication	FP	Food Production
CompB	Comparisons Between	FSE	Farm Scale Evaluation
Comp	Comparison	ID	Identification
Crop Prod	Crop Protection	IFM	Integrated Farm Management
Disadv	Disadvantages	II	Industrialisation of Agriculture
DM	Decision-Making	Imp	Implications
Ecol	Ecology	Ind	Industry
Econ	Economics	Info	Information
EFSA	European Food Safety Association	Intro Sp	Introduction of Species
Env	Environment	IPR	Intellectual Property Rights

Ethi	Ethical	IR	Insect Resistance
EU	European Union	LofK	Lack of Knowledge
FC	Future Crops	M&M	Management and Monitoring
FF	Food and Feed Regulation	NanoTech	Nanotechnology
NtoK NtoK	Need to Know, Nice to Know	S/H	Stakeholder
NTO	Non-target Organism	Situ	Situation
Pos	Positive	SJ	Scientific Journals
PP	Precautionary Principle	SR	Scientific Research
R&D	Research and Development	S-b-S	Step-by-Step
RA	Risk Assessment	Tech	Technology
Reg	Regulators	Trace/Label	Traceability and Labelling
RP	Regulatory Process	UK	United Kingdom
S/S	Science and Society	Under	Understanding
Sci	Science	US	United States
SE	Scientific Evidence	WTO	World Trade Organisation
SEv	Substantial Equivalence		

Chapter One

General Introduction

1 Chapter One: General Introduction

Part One: Summary of the introduction and research aims

1.1 Summary of the literature

Genetically Modified (GM) crops have the potential to benefit agriculture, the environment and society (see section 1.3); through the variety of traits which can be introduced. These traits have many potential benefits including: increasing yield, while decreasing the agricultural footprint (Phipps and Park, 2004; Pretty, 2001); addressing some of the issues associated with a growing population and malnutrition (Schrope, 2001); reducing farmers reliance on chemical inputs which would have financial as well as health implications (Huang et al., 2005) and providing new sources of energy, pharmaceuticals and bioremediation (Cockburn, 2004; Streatfield, 2001) (see section 1.3.1-1.3.6). However, the production mechanisms enabling the incorporation of such a wide array of traits, and the traits themselves, could possess inherent hazards that might compromise the safety of both human health and the environment (Wilson et al., 2004; Peterson et al., 2001) (see section 1.4); the latter being the focus of this study. If these risks are realised then there could be knock-on agricultural, environmental, economical, health, societal and/or ethical implications (see section 1.4). Over the last decade there has been a huge amount of effort spent on quantifying the environmental risks posed by GM crops (see section 1.5). While a number of issues are agreed upon, there is still a lot of debate about the science, the risks and the method of scientific risk assessment in the scientific literature (Johnson et al., 2007). The debate about the environmental risks posed by GM crops extends outside of scientific circles and has become a concern in wider society (see section 1.6). Societal concerns about the environmental risks fall into two categories: those which can be considered as scientific concerns and thus fall within the science-based regulatory risk assessment, and those concerns which fall outside of this. Both are equally valid as they represent real concerns of a stakeholder group with the power to halt commercialisation, both commercially in terms of market force and politically in terms of voting power, (see section 1.6).

Societal concerns have been driven by a number of factors. The media and campaign organisations have had a large role to play in introducing society to the concerns about GM crops (Bonny, 2004; Burke, 2004; Kasperson et al., 1988) (see section 1.6.5). They are, however, not solely to blame for the societal response to GM; the way industry, governments, regulators and scientists have dealt with societal concerns both in relation to GM crop and other scientific innovations, have also had an impact. There are a number of underlying factors that influence societal perceptions of a new technology (Finucane, 2002; Gaskell, 2004; Slovic, 1992). These include, to name but a few: people's level of understanding about the science, the risks and agriculture in general (Gaskell, 2004; Frewer, 1996); their trust in those responsible for ensuring environmental safety (Earle and Cvetkovich, 1995; Finucane, 2002); their concerns about agendas (House of Lords, 2000; Pollara and Earnscliff, 2001); plus the differences between layperson and expert assessments of risk (Siegrist and Cvetkovich, 2000; Sjoberg, 1998; Slovic, 1992) (see section 1.6 for a comprehensive overview). Differences in perception of the environmental risks and how these risks may (or may not, in the case of non-scientific risks) be addressed have occurred between those involved in the regulatory process and those within the wider society resulting in a great deal of societal concern and tension. These sources of societal concern need to be addressed if GM crops are to be accepted.

The science-based environmental risks are dealt with in the regulatory processes (EC, 2001; EC, 2003b), which govern the deliberate release of GM crops in almost every country worldwide (see section 1.5). While the underlying principle of ensuring environmental safety is the same globally, the methods vary dramatically (Ervin et al., 2003; Nap et al., 2003) (see section 1.5.1-1.5.3). Some countries are product-based in their approach like the US and Canada; whilst others, like the European Union (EU) are a process-based (Guehlstorf and Hallstrom, 2005; Jaffe, 2004; Nap et al., 2003), (see section 1.5.2). The EU regulatory process is the focus of this thesis, as it is the GM debate in Europe that is of interest. The EU regulatory process is considered by some to be the most

stringent in the world (Nap et al., 2003); yet there are others who have questioned the regulatory scope and validity of the review process (Frewer, 2004) (see section 1.6.2). The scope has been a concern for both sides of the debate, with proponents often feeling that it is too broad and opponents frequently deeming it too narrow (Finucane, 2002). Those who criticise the regulatory process as being too broad usually focus on the scientific requirements, while those concerned by the narrowness of the process often question why only the scientific risks are considered, and advocate the inclusion of economic, societal and ethical risks as well (see section 1.6.2 & 1.6.7). Criticisms usually centre on society's trust in the regulatory review process and those involved in it (Lonroth, 2003; Munnichs, 2004) with critics usually questioning the independence and expertise of those on the committees (Levidow, 2004), urging the inclusion of wider selection of stakeholder representatives (Gaskell, 2004; Wolt and Peterson, 2000) and greater openness and transparency of the process (Davies and Wolf-Phillips, 2006; Plous, 1991) (see section 1.6.7).

1.2 Summary of the research aims

In reviewing the literature, there is a great divergence of opinion between the various stakeholders within the debate and, in more general terms, between science and society when it comes to perceptions of both the environmental risks and the appropriateness of the regulatory process (sees sections 1.4-1.6). These will need to be addressed if society is ever going to accept the inclusion of GM crops in European agricultural production. To include such societal concerns in the regulatory process is not straightforward. Societal concerns vary in their nature, some being easily quantified and others purely qualitative and while accepted thresholds for some could be readily identified, for others it would be almost impossible. However, a way in which this could be done has been proposed by Johnson et al., (2007) who recognized that though risk assessment is purely there to quantify scientific risks, the wider process of risk analysis is where the societal concerns should be incorporated (see Johnson et al., 2007 for a comprehensive overview).

The aim of this thesis is not to test the hypothesis that different stakeholder groups perceive the environmental risks and regulator process differently and therefore requires different management goals (MG) and assessment endpoint (AE); rather it is to explore this hypothesis and identify the different groups' concerns. In order to achieve this, three research aims have been identified:

Research Aim One: To assess different stakeholders' perceptions of the environmental risk associated with the deliberate release of GM crops.

Research Aim Two: To assess different stakeholders' perceptions of the current regulatory process governing the deliberate release of GM crops.

Research Aim Three: To address management goals and assessment endpoints that could be used as drivers of the current regulatory process in order to address the stakeholders concerns.

The objectives in relation to each of the research aims are then two fold: firstly, to identify the key concerns of five different stakeholder groups, in relation to three issues: the environmental risks, the current regulatory process, and MG or AE which can be utilised to address their concerns; and secondly, to identify areas of discord and commonality between stakeholder groups in relation to these issues. The research aims will be achieved through the analysis of a series of semi-structured interviews carried out with representatives of each of the main stakeholder groups involved (Chapter Two, section 2.1). The semi-structured interview will enable representatives to share their concerns in relation to each of the research aims, but still be structured enough to allow comparisons between the interviews to be made (Oppenheim, 1992; Wengraf, 2001) (Chapter Two, section 2.1.1).

1.2.1 Research aim one

The stakeholders' perceptions of the environmental risks associated with the deliberate release of GM crops are dealt with in Chapter Three. It was investigated via the utilisation of four interview question: the first, gaining a insight into the

representatives perceptions' of the environmental risks in general; with the other three gauging the views of the representative in relation to the specific environmental risks: gene flow, non-target effects and alterations to farm management practices (issues which have been the focus of the scientific debate, section 1.3).

1.2.2 Research aim two

Chapter Four, focuses on the stakeholders' perceptions of the current regulatory process. Again, this was investigated using multiple research questions: the first, identifying the stakeholders' views of the regulatory process in general; with the final three looking at specific aspects of the process: the regulatory scope, the review process, and areas where improvements can be identified.

1.2.3 Research aim three

The final results chapter, (Chapter Five), considers the potential MG and AE the stakeholder representatives identify. For this only one interview question is as utilised, directly asking the stakeholders whether they can identify any MG or AE they would like to see driving the regulatory assessment of GM crops.

While this thesis concentrates on the GM debate, the conclusions drawn have wider implications in relation to future scientific innovations and societal acceptance. Society has a history, when it comes to scientific innovations, of either taking a long time to accept them as was the case for the smallpox vaccine (Braun, 2002) or rejecting them completely (e.g. food irradiation) (Munnichs, 2004) (see section 1.6). The GM debate provides scientists, regulators, industry and indeed society, with the opportunity to learn about societal acceptance of scientific innovation, which could then be applied to future innovations. The general discussion of this thesis (Chapter Six) synthesises the findings of the three research chapters (Chapters Three-Five) and suggests ways in which these can be integrated in to the wider context of scientific innovation.

Part Two: Literature review – Biotechnology: the benefits and risks, regulations and societal debate.

1.3 Biotechnology: its use within agriculture and the potential benefits

"*Modern biotechnology, also known as genetic modification and genetic engineering, is the name given to the artificial transfer of DNA from one organism to another, so allowing the recipient to express traits or characteristics normally associated with the donor*" (Conway, 2000).

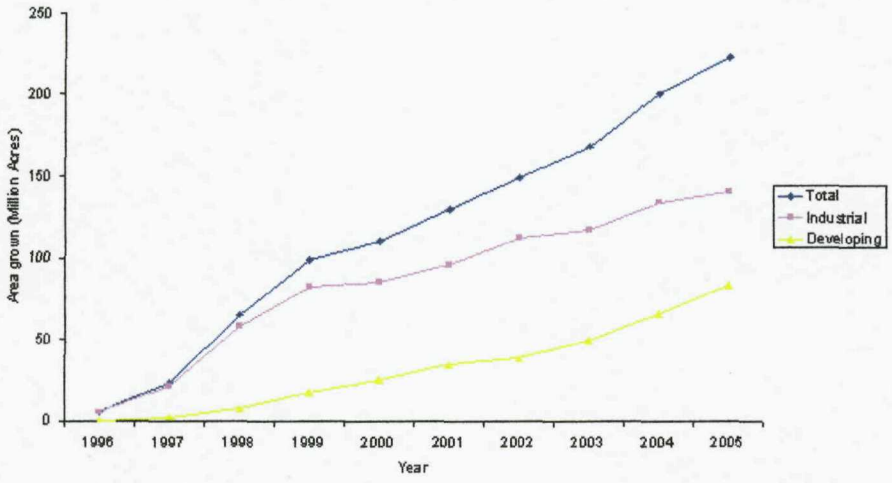
Within nature some organisms/ trait combinations would never occur, without the use of biotechnology, as barriers due to sexual selection make it impossible and therefore even with the advances in conventional breeding some trait/crop combinations would be highly unlikely, for example getting a *Bacillus thurengenesis* (Bt) gene into a cotton plant or insertion of a jellyfish gene into a tobacco plant (Kwon et al., 2001) even though there are those who would argue that GM is just a continuation in the rapid advancements made in agriculture over the last century (Conner et al., 2003); which included: "*artificial manipulation of chromosome number; the development of addition substitution lines for specific chromosomes; chemical mutation; mutation through radiation; chromosomal rearrangements; and cell tissue culture approaches (embryo rescue and embryo transfer)*" (Conner et al., 2003). The genetic gains for plant breeding and agriculture of these developments are clearly evident. GM has allowed plant breeders to respond much more quickly to consumers' demands (National Academy of Science, 2000b; Snape, 2004), it also offers a much wider potential array of donor traits (National Academy of Science, 2000b).

There has been debate about whether currently commercialised GM crops provide farmers with benefits (Phipps and Park, 2002), the concern being that it is the companies producing these crops who reap the rewards. However, it is hard to explain the phenomenal uptake in the crops globally (with the exception of

Europe), (refer to figure 1.1), without assuming that farmers themselves see some benefit in using the currently commercialised GM varieties (Herdt, 2006).

The first commercially cultivated GM crop was GM soya in 1995 (James, 2005a). Since then, the majority of the crops commercially cultivated fall into four varieties: soya; maize; cotton; and oil seed rape (or canola). The main four crop varieties are aimed at the lucrative developed world markets, of America, Canada, Australia (and initially Europe), but in recent years uptake in developing countries has increased, notably in 2004 where the annual increase in uptake exceeded that of the developed world for the first time (James, 2005b). There are other GM varieties grown, most notably in developing countries, such as cavassa, papaya, bananas, tobacco and rice (Herdt, 2006; Nuffied Council on Bioethics, 2004; Paarlberg, 2002).

Figure 1.1: Commercial uptake of GM crops from 1996 to 2005 (take from: James, 2005)



In 2005, the USA was responsible for growing 55% of the global biotech land area, followed by Argentina, Brazil, Canada and China as the principle adopters of agricultural biotechnology (James, 2005b). The majority of the crops have either one of two traits: herbicide tolerant (HT); or insect resistant (IR), (refer to table 1.2) (James, 2005a; Uzogara, 2000a). In some cases they have both traits

incorporated. There are other traits which have been used, such as disease and virus resistance (Bannon et al., 2004; James, 2005b; Snow et al., 2005; Uzogara, 2000b; Yan and Kerr, 2002) but the global uptake of these crops and traits is minimal in comparison to HT and IR crops.

While the proposed benefits of GM crops are often interrelated, they are discussed below under the broad headings of: improvement to agricultural practice, addressing abiotic factors limiting agricultural production, GM's role in alleviating hunger, the nutritional benefits, and the medical implications.

1.3.1 Improving agricultural practice by increasing yields and reducing inputs

Farming, like any business is dependant on the cost of the final product being larger then the cost of the inputs. In terms of the final product in farming that is directly related to the size and quality of the final crop yield, while inputs encompass the operating resources used in generating the crop. GM, in the same vein as improvements in conventional methods, potentially gives farmers a way of reducing their input burden while increasing their yield, thus enabling them to maximise their profit.

When considering the effect the adoption of GM crops has had on yield and the reduction of input costs, the data shows a lot of variability. This is something one would expect as both yield and the amount of inputs required will differ significantly depending on numerous factors such as: the crop, the trait, the environmental factors, the pest species, the country, even the region, perhaps the farm size, and certainly the year; this is something which is supported in the literature (Falk et al., 2002b). It is therefore difficult to draw strong conclusions and it is easy to contest the findings (Aerni, 2005; Falk et al., 2002b; Uzogara, 2000b). In a study for the National Centre for Food and Agriculture Policy, researchers identified the potential economic benefits to the US farmer when growing a number of different GM crop and trait varieties (Gianessi et al., 2003).

Their findings have been summarised in table 1.2; and echo a trend shown in a comprehensive review by Phipps and Park (Phipps and Park, 2002) that in general GM IR crops show an increase in yield and decrease in chemicals inputs and GM HT crops show a reduction in chemical inputs, the extent of which, however, is variable.

Interestingly some of the more noticeable benefits to agriculture from GM crops have not come directly from increases in yield or reduction in chemical inputs but indirectly. The reduction in deaths attributed to pesticide poisoning with the use of IR crops, as a result of the reduced number of chemical pesticide applications required, is one of the most noticeable benefits for farmers in the developing world (Huang et al., 2002). Pesticide poisoning is a real issue in the developing world that has economic (loss of work force) as well as a human health effects. Another indirect benefit is the reduction in tillage and even the adoption in some places of no-till practices which has positive economic and environmental implications (Vangessel et al., 2001a). Also the reduction in the number of sprayings required has had a knock-on effect in reducing the amount of fuel used, in both the production and spraying of these chemicals; it is estimated that the technology has reduced the global agricultural release of green house gases significantly, *"by over 10 billion kg which is equivalent to removing 5 million cars from the roads for a year"* (Brookes, 2004).

In the future there will be more pressures placed on agricultural production. An increasing population (Dyson, 1996; Matson et al., 1997; Plantinga and Miller, 2001; 2001; van Vliet et al., 2003) and demographic change (Matson et al., 1997; Tilman et al., 2001), will require more land for urban dwellings and infrastructure. Climate change is expected to alter land productivity/availability (Abildtrup et al., 2006; Conde et al., 2006; Fuhrer et al., 2006; Gay et al., 2006; McLeman and Smit, 2006; Ramankutty et al., 2006; Streck and Alberto, 2006), and is reinforcing an increasing environmental awareness (van Vliet et al., 2003) which is resulting in the push towards more sustainable methods of farming (Levidow and Carr, 2000a; Mark et al., 2006; Martins and Marques, 2006; Tilman et al., 2001). All of

these will put pressure on farmers and agriculture to try to produce greater yields from less land, reducing our environmental "footprint" and allowing land to be freed up for urbanisation, wild life, infrastructure, recreation and leisure use (De Oliveira et al., 2005; Hoekstra and Chapagain, 2007; Schmidt and Bothma, 2006; Schmit and Rounsevell, 2006). Pretty, (1998), in his book The Living Land, reviews these issues in detail.

Table 1.2: An overview of the yield and pest protection effects for USA farmers of using GM crops in 1999 (Gianessi et al., 2003).

GM crop and Trait	**Yield Effect**	**Chemical Input Effect**
IR (Bt) Corn	The primary benefit of Bt corn is the increased yields, which in 1999 were estimated at 66 million bushels being saved from corn borer attack. This equates to nearly 500,000 acres.	There were modest reductions in the amounts of corn insecticide used, since the introduction of Bt corn.
IR (Bt) Cotton	Cotton production has increased by (USA) 260 million lbs per year, with net revenues being estimated to have increased by US $99 million	It is estimated that cotton growers reduced insecticide use by (USA) 2.7 million lb and made 15 million fewer insecticide applications per year.
HT Cotton	N/A	Until GM there were no efficient broadleaf herbicides which could be used over cotton without damaging the crop, so treatment was time consuming as it was required to treat the weeds without contacting the crop. The introduction of GM HT cotton has led to a reduction of the number of herbicide application by 19 million
HT Soyabean	N/A	Pre-GM growers would apply 3 or more herbicides to reduce weed cost. GM HT crops resulted in a reduction in the number of herbicide application by 19 million. Thus the primary benefit has been the reduction of weed control costs by US $216 million in 1999.

GM potentially could be utilised as a tool to allow farmers to maximise their yield, whilst minimising their inputs, thus achieving major sustainability benefits. Some do argue that conventional breeding can be successfully used to do this (Aid, 1999; Goklany, 2000) however others feel that yield increase ceilings have

already been met through conventional methods and there is not that much more potential to increase yield further (Conway, 2000; Matson et al., 1997).

1.3.2 Addressing abiotic factors limiting agriculture

As already discussed the amount of land available to farmers in the future will be limited and potentially reduced (The Food and Agriculture Organisation, 1999). Crops which enable farmers to utilise land which was previously unavailable to them will be of massive benefit.

A number of GM crops are being developed which tolerant a range of abiotic stresses, including drought, salinity and cold (Dalal et al., 2006; Weil, 2005). These types of crops could be hugely beneficial especially in parts of the developing world, where the capacity to utilise marginal lands for agriculture could have significant economic and social benefits. For example 1.6 billion hectares of the worlds' arable land is affected by drought (James, 2005a) the majority of which is in developing countries, and in the future more drought is predicted (Burston, 2006). The engineering of a drought tolerant crop has long been an objective of conventional breeding (VanGessel et al., 2001b; Weil, 2005), as well as an objective of the biotech sector. Progress at the moment is slow, due to the complexity of the traits involved (a common issue with traits which confer abiotic tolerance), and the current understanding about the genes controlling them (Weil, 2005).

Abiotic stress tolerant crops are also being modified specifically for using in developing countries. Cornell University in 2002 successfully tested a strain of rice which effectively maintained yield under drought, cold and unfavourable saline conditions (Dalal et al., 2006). The important aspect of this work as far as Developing Nations are concerned is that the researchers plan to seek patent protection for the modification which will ensure public availability of the modification, particularly for farmers in developing countries. Abiotic resistance is definitely an important future trait, with a number of crops being field tested

around the world in developing countries: frost tolerant potatoes in Bolivia, cold tolerant tomatoes in China, moisture- stress resistant rice in Thailand, salt tolerant wheat in Egypt and moisture-stress resistant *Brassica* in India (The Food and Agriculture Organisation, 1999).

Resistance to abiotic stresses will certainly be beneficial for agriculture and food production in the future, with less land available to grow crops on and more stresses as a result of climate change. This would represent a major opportunity. The question is whether the complex traits which confer abiotic resistance can be engineered into the plant without too much cost to either the plant in terms of resource allocation or industry in terms of the economic feasibility of production and commercial viability.

1.3.3 GM role in alleviating hunger

The United Nations (UN) along with other international organisations announced that the world is facing such serious problems with global food and nutrition security in the 21st century that it cannot turn away from GM (Schrope, 2001). This has been supported by similar assessments made by other prestigious bodies such as the National Academy of Science (National Academy of Science, 2000a).

Now some will argue that GM crops are unnecessary as it is the distribution of food which is the issue, not the quantity, as there is currently more then enough calories of food produced in the world (The Food and Agriculture Organisation, 1999). This argument has two critical flaws, identified by The Nuffield Council on Bioethics (2004): Firstly, there is only enough calories of cereals produced if you do not take into consideration what is required to feed cattle and poultry, the conversion of fodder into meat and milk requires 6 times the amount of crop than if people just ate the crop directly. Thus we only have enough food crops to feed the world if we abandon consuming meat, dairy products eggs and poultry. Secondly, the land to grow staple crops on and the cash to buy them would also need to be distributed evenly. Thus it is fair to say that while the utopian dream of

even distribution of food might be ethically commendable over the utilisation of a new technology, it is logistically and fundamentally flawed.

The improvements in yields that have been demonstrated in GM crops already commercially cultivated such as the HT and IR varieties. Yield increases brought about through GM could play an important role in addressing the increasing global demand for certain staple crops, especially if this technology can be used in crops which will aid Developing Nations where yields are much lower (Nuffied Council on Bioethics, 2004) in which case the benefits could be even greater. A good example of a GM crop being developed which is aimed at Developing Nations is abiotic stress resistant rice (Nuffied Council on Bioethics, 2004). It is estimated that the modified variety has the potential to increase yields under poor conditions by as much as 20%, however field trials are not set to take place for several years (Weil, 2005).

GM crops do have the potential to address the issue of food security through improving yield and reducing losses due to pest attacks, secondary infestations and loss of labour force, reducing the cost to produce the crops due to decreased input requirements. They are not however a silver bullet and need to be carefully used in combination with other farm management practices to ensure the largest benefits. They are however, as the Nuffield Council on Bioethics (2004), identifies, "*a more appropriate solution then the alternative of leaving them* [Developing Nations] *to rely on food donations supplied by the World Food Program and other organisations*".

1.3.4 Nutritional benefits

With an increased awareness of the nutritional deficiencies of Developing Nations and Developed Nations becoming increasingly health conscious, GM technology certainly could possess numerous benefits, if nutritional traits can be incorporated. Plants can be designed and developed to contain nutritionally desirable

components such as: lysine, methionine, zinc, iron and vitamins, including vitamin A (Falk et al., 2002a; Uzogara, 2000b).

Golden Rice is a great example of how plants can be modified to aid the fight against the nutritional deficiencies in developing countries, see (King, 2002). Golden Rice has been awaiting field trialling since 2000, delays in trialling have been attributed to the debate in Europe over the risks associated with GM crops (Nuffied Council on Bioethics, 2004). The amount of Vitamin A which can be appropriated and the moral and ethical implications attached, have been of much debate (Weil, 2005).

Nutritionally altered varieties are also being developed for Western markets, mainly on the grounds of the potential health benefits. Starch, oil and protein compositions have been altered to improve the nutritional values of various food (Chassy et al., 2004; Falk et al., 2002a; Hunt, 2001; King, 2002; Kishore and Shewmaker, 1999). The most notable example is the development of a new strain of potatoes which contains between 30-60% more starch making the potatoes less absorbent and therefore producing a healthier chip (Uzogara, 2000b). Another example is the development of a sweetener from the fruit of the African vine, *Pentadiplandra brazzena*, which is a heat stable protein 500 times as sweet as sucrose yet lacking the bitterness that could potentially be a new form of low energy sweetener (Falk et al., 2002a).

Increasingly biotechnology has the potential to deliver real benefits in terms of the quality, safety and nutritional value of the food we eat. This is exemplified by the position the American Dietetic Association took in a recent paper (Bruhn and Earl, 2006), stating "*It is the position of the American Dietetic Association that agricultural and food biotechnology techniques can enhance the quality, safety, nutritional value, and variety of food available for human consumption and increase the efficiency of food production, food processing, food distribution, and environmental and waste management. The American Dietetic Association*

encourages the government, food manufacturers, food commodity groups, and qualified food and nutrition professionals to work together to inform consumers about this new technology and encourage the availability of these products in the marketplace". It is worth noting that the organisation has some links with multinational food companies.

Nutritionally it is clear that GM technology can potentially benefit mankind across the globe. Most of these GM crops products are still in the early stages of development, and will require refining in order to produce the levels of nutritional benefit that will satisfy critics, however the potential is certainly there and only time will tell if it is realised.

1.3.5 Medical implications

One of the biggest potentials with GM technology, is that it could be used to treat disease and combat various maladies (Estrada, 1998; Paoletti and Pimentel, 1996), which could completely change preventative health care (Streatfield, 2001). There are predominantly two distinctive methods for producing biopharmaceutical crops. Plants can be modified so that they produce substances which can be extracted and then refined into compounds that can be used or plants could themselves produce vaccines which would be administered through the consumption of the plant (Streatfield, 2001).

Vaccines are being engineered into crops such as corn, potatoes and bananas although their development is only at the early stages (Nuffied Council on Bioethics, 2004). The most noted examples are the GM tomatoes, produced at Cornell University, which are hoped will provide a vaccine against the Norwalk Virus (a cause of dysentery) and GM bananas which, have been modified to produce a vaccine against Hepatitis B (Paoletti and Pimentel, 1996). While currently GM crops producing vaccines are a long way off commercialisation, they have great potential as healthcare tools. Many companies are position themselves to become suppliers of a wide range of biotechnology products, including bioactive therapeutic proteins, blood proteins and animal health

products (Falk et al., 2002a). If these crops can be commercially realised then they definitely do possess huge benefits for future healthcare.

1.3.6 Industrial applications with associated environmental benefits

A number of crops are being modified for industrial applications; these include plants which could be used for bioremediation, industrial enzymes and oils.

With increasing pressures placed on governments and industry to find alternatives to fossil fuels, biofuels are becoming an attractive alternative. Biofuels are not novel to GM, however GM technology could enable them to be produced more efficiently by decreasing input costs (Phipps and Beever, 2000; Phipps and Park, 2002). The major advantage of GM is the ability to alter the plants' oil and sugar content, for example the engineering of plants to enhance their sugar composition, to serve as higher productivity industrial feed stock ethanol (Konig et al., 2004). This will allow them to be used as a renewable energy feed stock, an attractive prospect in the face of climate change, although there are still questions surrounding the quantities which would be required and the competition with food production for an already limited growing space.

GM of plants to make them efficient phytoremediators also has huge potential environmental benefits, as well as economic ones. For instance GM plants could be used to restore soil health and re-vegetate contaminated waste sites. An example that is being trialled is the modification of yellow poplar trees in order to have the ability to extract mercury from the soil, the plants then convert the toxin into an inert form. The gene was acquired from a soil-borne bacterium that is mercury resistant (Snow et al., 2005).

The viability of using GM crops as sources of biofuels or bioremediation will depend upon the efficiency and effectiveness of the GM crops, however the potential is certainly there.

1.3.7 Summary

Potentially the use of GM crops could yield a number of economic, environmental, agricultural and societal benefits. Many of these benefits however, rest on crops that have yet to be commercialised, or in some cases, developed. The benefits of the crops that are currently commercialised are disputed scientifically; what cannot be disputed is the extent to which they have been taken up by farmers over much of the world, (with the exception of Europe). From this, it can be concluded that GM presents itself as a potentially beneficial tool for agriculture, its wider implications being highly dependant on those who are driving it and the barriers put in front of it.

1.4 The potential risks associated with agricultural applications of biotechnology

Proponents of biotechnology often state that *"it is going to be an essential partner, if yield ceilings are to be raised, if crops are to be grown without excessive reliance on pesticides and herbicide, and if farmers on less favoured lands are to be provided worth crops that are resistant to drought and salinity, and that can make more efficient use of nitrogen and other nutrients."* (Conway, 2000). Others, however, have stated that these arguments for the benefits of GM technology are not currently supported by scientific consensus or comprehensive comparisons to agricultural alternatives (Peterson et al., 2000), although one would have to concede that scientific consensus on an issue as contentious as GM would not be easy to gain. Alongside GM's potential to benefit agriculture, the environment and mankind, it also has the potential to cause harm. The inherent properties of the crops which provided the benefits also result in a number of intrinsic hazards.

GM organisms have the potential to be significantly more novel than new conventionally modified organisms, incorporating as they sometimes do genes from distant or unrelated organism in combinations that are unlikely ever to have

occurred naturally. Indeed Beringer, (2000) in a speech given for the 8th BES Lecture concurs, stating "*a common concern about the use of GM crops is that they will give rise to combinations of genes that could not arise naturally, and that such combinations might confer extra selective advantages or disadvantages.*"

Of course the risk posed to either human health or the environment, as Tiedje et al., (1989) point out, is dependant upon the survival and reproducibility of the GMO, the interactions it will have in the environment with other species, the potential for it to spread beyond the point of introduction and the effects it could have in altering the physical environment. Thus when considering the potential risks, one has to look at GM crops in a very case-dependant fashion, as some will differ little from the parental organism while others will be dramatically different.

When considering the potential risks posed by GMOs, comparisons are drawn between GMOs and the introduction of non-native species, (Beringer, 2000; Teidje et al., 1989); mainly because "*they* [GM crops] *bear novel genes, and usually express novel traits, thus are novel organisms and as such will constitute non-native introductions in every environment into which they are released*", (Scientists Working Group on Biosafety, 1998). It is easy to draw comparisons between the two, as Teidje et al., (1989), identified, "*a plant may persist in a new range because in the course of immigration it has escaped its native herbivores and has not attracted new herbivores. A transgenic plant may experience the same outcome with insertion of genes that control the production of the proteinase inhibitors.*" In comparing GMOs in general with introduced species, Peterson et al. (2000), claimed that the immediate ecological impacts of GM crops are likely to be minimal as they will usually be more dependant on human support. However considering GMOs on a case basis, then some may have novel traits that will increase their ability to survive outside managed conditions or give them a great benefit under certain conditions. Abiotic stress resistance, for example, could in fact be a much great environmental risks than that of a comparable introduced species (Regal, 1999).

GM crop are not the only form of agricultural variety to have the potential to become invasive species; there are numerous agricultural examples: maize, wheat and biocontrol agents, to name but a few; indeed 128 species of introduced crops in the US have become serious weeds, (Pimentel, 2000). However as Peterson et al.(2000), stressed there has been little public concern over these, or indeed over many of the introduced non-native species (like rhododendron) which are causing actual environmental harm. In fact many of the environmental risks which are associated with GMOs, and GM crops in particular, are also present in conventionally modified varieties. These too can be invasive, are subject to gene flow, can be bred to withstand generalist herbicides or to improve agricultural efficiency, mutated and irradiated to form new varieties yielding new traits, yet these are not considered as environmental threats in the same was as GM crops.

The transformation of a plant via GM methods, rather than conventional breeding, allows more precision in the transfer of genes and therefore traits (NRC, 2002; Snow and Palma, 1997). There are those proponents of GM technology who will go as far as saying the this greater precision could decrease hazards associated with the deliberate release of GM crops as compared to conventionally modified ones, (Brill, 1985; Davis, 1987; Scientists Working Group on Biosafety, 1998) as traditional breeding typically results in the inclusion of deleterious alleles linked to the desired beneficial genes, (Ervin et al., 2003). When considering whether the environmental risks are lessened due to the precision of genetic transfer involved in GM as opposed to conventional modification techniques, Tiedje et al., (1989) gave a nice summation: "*although the capability to produce precise genetic alterations increases confidence that unintended changes in the genome have not occurred, precise genetic characterisation does not ensure that all ecologically important aspects of the phonology can be predicted for the environments into which an organism will be released.*"

A number of similarities can be drawn between the environmental risks conventional crops can pose and those posed by GM crops. Especially considering that many of the current GM crops, have inserted genes (and thus traits) which could be conventionally bred into a crop, HT for example. What needs to be considered is whether the (environmental) risks are inherent to the production methods or the individual traits inserted.

The rest of this section will consider the potential risks GM crops could pose in more detail. Firstly, considering the risks inherent with the production of GM crops, and secondly considering three particular category of environmental concerns in more detail, two of which are identified by Ervin et al., (2003), as the main categories of hazard to emerge: the transfer of genes; and impacts on non-target insects and plants. Ervin et al., (2003) also identified the evolution of resistance as a category, this will be considered as part of a larger category: the implications on farm management practices, of which resistance is part, but also considers a number of other relatively new environmental concerns about GM, some of which have emerged from the UK Farm Scale Evaluation (FSE) investigations,(Firbank, 2003; Firbank et al., 2003).

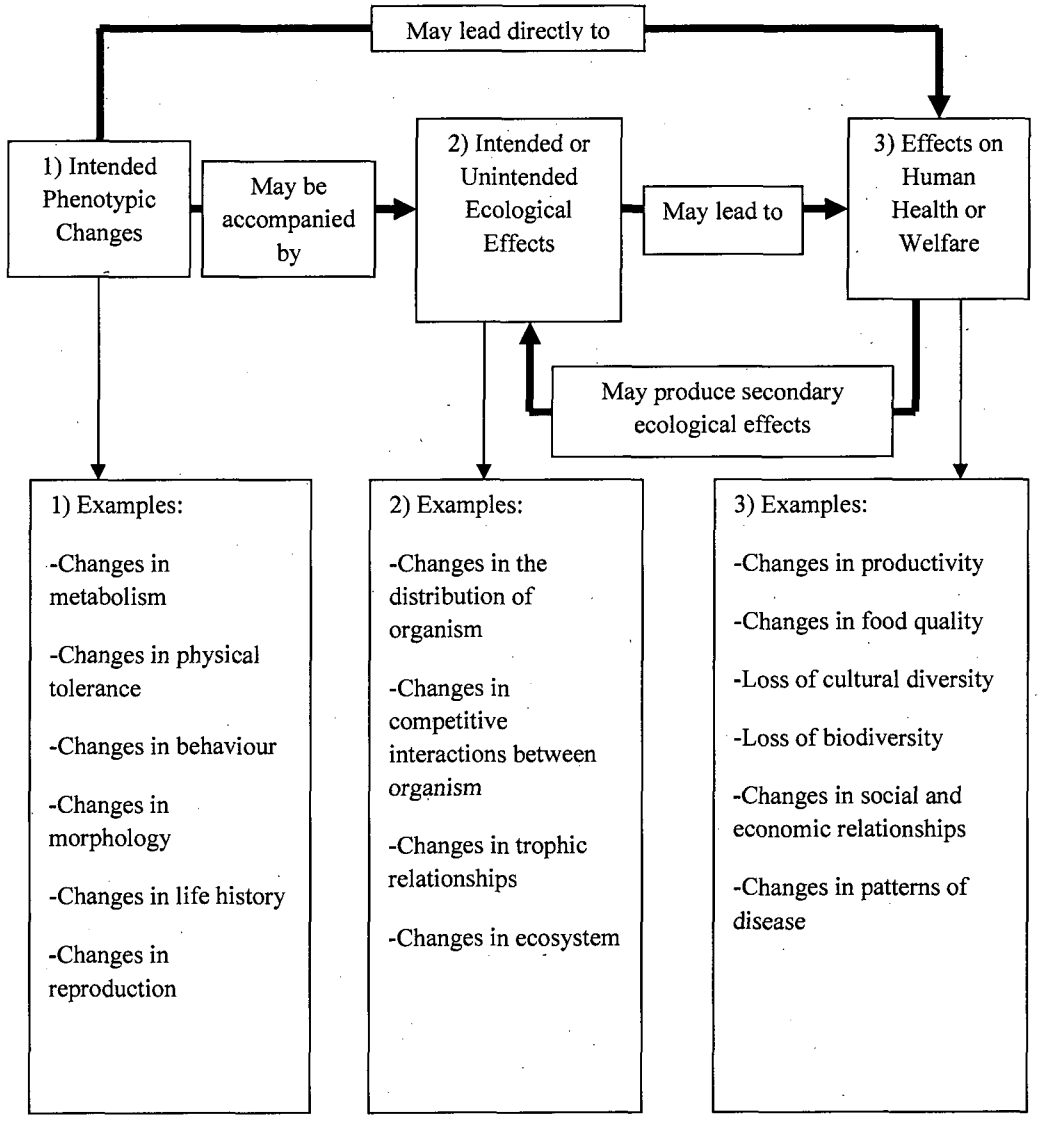
1.4.1 The risks associated with the plant transformation process

There is a concern that the actual transformation process might have significant genetic consequences attached (Wilson et al., 2004). The concern is that plant transformations might result in unintended insertions, deletions and mutations, in both functioning and non-functioning regions of the genome (Kaya et al., 2000; Weigel et al., 2000). These can be at the site of the transgene insertion (Forsbach A. et al., 2003; Kohli et al., 2003; Makarevitch et al., 2003; Windels et al., 2001), or genome-wide (Labra et al., 2001; Sears et al., 2001). As the typical transformation methods require tissue culturing (to regenerate the intact plants from the single cells that have been transformed), and have either been "infected" by pathogenic organisms (*Agrobacterium tumefaciens*), or bombarded with tungsten particles (Jain, 2001; Kohli et al., 2003). These unintended effects of the transformation process might result in an altered biochemistry of the transgenic

plant (Kuiper et al., 2001), and this will result in phenotypic changes, the result of which could have agricultural, environmental and human health implications (Wilson et al., 2004). The real concern is that the mutational changes could be unpredictable and would be difficult to identify, even with extensive biochemical testing (Kuiper et al., 2001).

When considering the risks posed by a GM crop, as already stressed, there are numerous factors which can influence whether the crop poses any risk to the environment, including survivability, potential to spread, potential interactions and effects on the physical environment. All of these factors will in someway be influenced by the inserted gene and phenotypic trait. The manual produced by the Edmonds Institute (Scientists Working Group on Biosafety, 1998) discussed the environmental and human health hazards which could result from phenotypic changes brought about but the insertion of the transgene result in both environmental and human health/ welfare effects, (figure 1.2).

Figure 1.2: Taken from, (Scientists Working Group on Biosafety, 1998), identifying the relationships between the intended phenotypic changes and the ecological, human health and welfare effects. For a comprehensive overview of examples of the potential ecological, human health and welfare effects refer to Appendix A in (Scientists Working Group on Biosafety, 1998).



This review is going to concentrate on the environmental risks, as these are most pertinent to the study. For a comprehensive overview of the literature associated with risks refer to table 1.1 (appendix one).

1.4.2 The transfer of genes

The transfer of the transgene from a GMO to a non-GMO can be achieved in two ways. The first is classed vertical gene transfer (or flow) and this happens between two sexually compatible plant species to form a hybrid containing the transgene. The second is classed as horizontal gene flow; horizontal gene flow is the movement of genes between disparate, unrelated species, such as between plants and microbes. Horizontal gene flow is discussed more theoretically than practically since it has never been shown to happen with transgenes, (Stewart, 2005). The majority of concerns are related to human health considerations and so will not be discussed in detail here. For a review of horizontal gene flow refer to, (Kleter et al., 2005; Nielsen and Townsend, 2004).

One of the main environmental concerns about GM crops is the potential for the transgenic gene(s) to flow from the crop to either other crops (non-GM or GM with other traits) or wild relatives, resulting in what some called genetic contamination or pollution, but in this report will be termed transgenic hybrids. Dale et al., (2002), identify four basic elements which determine the likelihood and consequences of gene flow: pollen movement, synchrony of flowering, sexual compatibility, the ecology of the recipient species and the nature of the transgene.

The majority of scientific research has been directed at pollen flow, and as a result there is now extensive literature on the distance of pollen movement, (Wilkinson et al., 2003a; Wilkinson et al., 2003b). The distance pollen travels is heavily influenced by the way in which it is dispersed, i.e. whether it is dispersed in the wind or relies of a vector such as pollinator for dispersal. An understanding of pollen dispersal has been key to setting out separation distances (between GM and non-GM crops). However, pollen transfer on its own does not consummate gene flow. Hybrids need to be produced and survive to pass on their genes to the next generation and for them to have the potential for introgression. Even if the pollen can disperse to wild relative and non-GM crops they still need to be sexually compatible if hybrids are to be formed, as well as flowering in synchrony. Ellstrand et al., (1999) present a comprehensive review of the compatibility of

crops with weeds and feral species. When considering the species commonly grown in the UK there is some variation in compatibility; sugar beet is considered to be of high compatibility, whereas wheat is considered minimal, with both oilseed rape and barley considered to be low (Raybould and Gray, 1993). Even with sexually compatible species which are within the range of pollen dispersal, there is still the issue of hybrid viability; whether the hybrid will survive and then go on to reproduce with the progeny expressing the transgenes. The viability of oilseed rape hybrids has gained the most attention, certainly within the UK, and as a result there are a number of reviews (NRC, 2002; Raybould and Gray, 1993; Scheffier and Dale, 1994; Scheffier et al., 1995). There is little doubt in the scientific community that genes will move from GM crops into the wild, (see Poppy and Wilkinson 2005). Ultimately the environmental consequences are not whether genes are passed into a wild relative or related crop, but the impact the wild relative/ related crop expressing that GM trait has on the surrounding ecosystem; this is often referred to as a the "so what question" (Gray, 2004).The environmental consequences will be dependant on two factors: firstly, the nature of the trait; and secondly, the biology and ecology of the recipient (Dale et al., 2002). When considering the nature of the trait, it is important to consider the fitness costs or benefits the incorporation of the trait will incur, and whether the trait would be selected for. For example it is easy to see traits that, outside of the agricultural environment, would be of little value, for instance herbicide tolerance is unlikely to confer any advantages outside managed agricultural areas; it might however come as a cost to the recipient to maintain, and as a result could reduce fitness, so is likely to be removed through natural selection. The general assumption that there is likely to be an environmental impact only if the novel trait confers environmental fitness is not necessarily the case, one which confers a reduced fitness if reoccurrence of transfer to a compatible specie occurs, might have a detrimental effect on the natural community of that species (Giddings, 2000).

Traits which might confer an environmental benefit needs to be considered more carefully, as these might be naturally selected for in a wild relative or non-GM crop environment. Potential GM traits which one could imagine conferring

beneficial advantages would be insect or virus resistance (Hails, 2005), future traits such as those tolerant to abiotic stress could also be perceived as potentially conferring beneficial traits. There have been numerous studies into the selective advantages insect resistance genes (in particular Bt) could bestow (Ramachandran et al., 2000; Stewart et al., 1997). One example from research by Snow (2002) shows that insertion of the Bt gene in wild sunflowers can increase seed production; another presented in a paper by Kelly et al., (2005) considers, comprehensively, the speed of resistance in pest species in relation to Bt transfer into wild relatives.

The movement of transgenic genes and the introgression of the resultant traits into related species is an issue both agriculturally and environmentally. Wild relatives which have incorporated transgenic genes giving them a selective advantage, could out compete other species and in doing so change their surrounding ecosystem. This would have big implications for the surrounding biodiversity. In an agricultural setting, gene flow to non-GM crops could have implications economically, if there is a premium on non-GM crops and socially as it could affect consumer choice. There is also the potential for GM traits to move between GM crops, thus potentially producing crops which express multiple traits. This has been the case in Canada where farmers have detected oilseed rape plants which are tolerant to three different types of herbicide (Barrett et al., 2001; Orson, 2002). This could be an issue in following rotations in later years where the farmers are trying to remove volunteers (Keeler et al., 1996). The extent to which a trait is likely to have introgressed and persisted in a wild or managed environment will depend on the nature of the trait; those which confer benefits outside the agriculturally managed system are more likely to be selected.

It should be remembered that a number of conventionally bred crops confer traits which could introgress and persist in wild relative populations. In fact Ellstrand (2001), suggests that classically bred crop-to-wild gene flow has resulted in the enhancement of weediness of weeds for 7 of the world's 13 most important crops, an example being *Sorghum halepense* (Johnson grass) in cultivated *Sorghum*

bicolour (Sorghum). However the ability of GM technology to incorporate genes and traits which would not be possible through conventional methods heightens the potential risks.

1.4.3 The impacts on non-target organisms (NTO)

Dale et al., (2002), defined non-target effects as "*undesirable effects of a novel gene (usually conferring pest or disease resistance) on "friendly" organisms in the environment*". It is hard however, when trying to manage pest populations not to affect other non-target organism or "non-targets", especially those with similar phenotypic and morphological characteristics, or rely on the pest species in some way (as a prey source or for parasitism). This is true of all forms of pest protection not just GM. It is argued that millions of birds and billions of insects, both harmful and beneficial (including pollinators and biological control agents), are killed each year in the United States alone as a result of pesticide use (Dale et al., 2002).

The impact a GM crop will have on non-targets will be dependant on the crop type, the inserted transgene and the resulting traits. The impacts can be generally sorted into direct effects: those resulting from a direct interaction between the non-target and the GM crop; and indirect effects: those effects on the non-target resulting from an intermediate that is itself affected by the GM crop in some way.

When considering the non-target effects of those crops and traits already commercialised, IR crops, expressing plant defence genes such as Bt, attract the most attention. The main targets of Bt crops are lepidopteron or coleopteran pests, such as the *Heliothis virescens* (Tobacco budworm) or *Ostrinia nubilalis* (European corn borer) or *Diabrotica vigifera* (Western Corn root worm). The primary concerns about Bt is that it will: a) have direct negative effects on non-targets which share similar characteristics as the as the pest species, and b) will have indirect effects on the food chain particularly on the predators and parasitoids of the target pest, figure 1.3.

The case of the Monarch butterfly is a good example of the potential direct effects of Bt and an example of the indirect effects would include the work done by Hilbeck et al., in Switzerland, on lacewings (Hilbeck et al., 1998a; 1998b), (table 1.3), although it should be noted that some would argue Hilbeck's work did consider the direct effects also. What should be taken from the Bt studies, is that Bt certainly has the potential to directly and indirectly affect non-target organism, under laboratory conditions. However laboratory conditions do not often emulate those in the field, they often do not take into account the likely exposure (i.e. Losey et al., (1999)), and look at worst case scenarios, using much higher concentrations of the toxin then would be found in the field, (i.e. Hilbeck et al., (1998b)). These exemplify the need to take both the hazard and exposure into account when performing a risk assessment (Johnson et al., 2007).

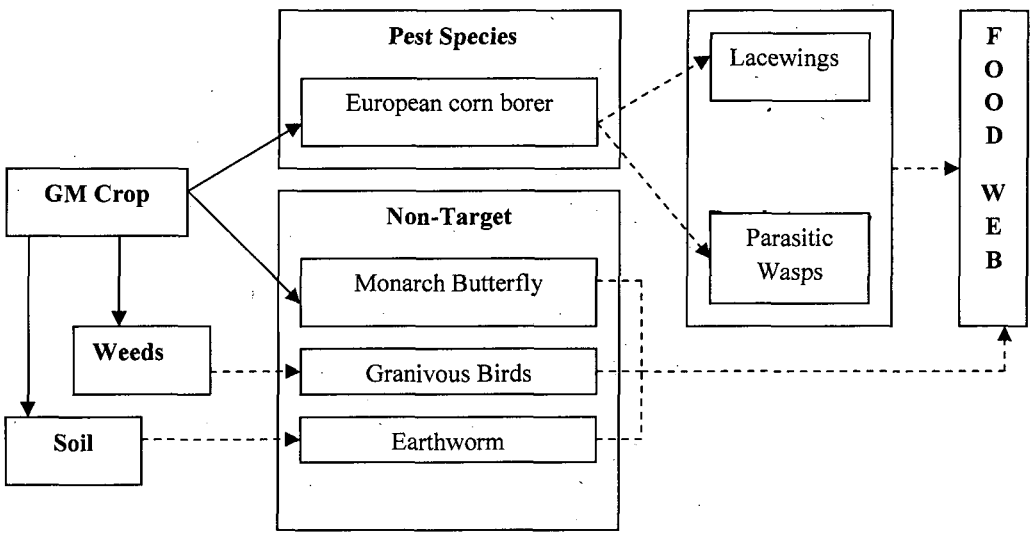
Table 1.3: Examples of research demonstrating the direct and indirect effects GM crops can have on non-target organisms.

The Monarch butterfly came to the world's attention after a paper was published in Nature (Losey et al., 1999), discussing the effects Bt pollen had when dusted on Milkweed and fed to Monarch caterpillars. The experiment was meant to emulate the potential in the field of pollen drift, milkweed which often grows at the edges of fields and is the primary food source for Monarchs, could be contaminated by GM pollen expressing the Bt genes. The report was only a initial study into the potential worst case scenarios, as it only considered the hazards not the potential exposure. Nevertheless it generated a lot of interest in the media and also a lot of concern from NGOs and the general public. As a result a number of other studies were commissioned (Sears et al., 2001), which concluded that in the field the Monarchs are not at risk as "*over all exposure to the Bt pollen is low*". There have however still been questions raised about the long-term effects of low level exposure to Bt pollen on the Monarch larva survival and fitness (Standley-Horn et al., 2001).
Hilbeck et al., (1998a; 1998b) showed two things, firstly that lacewings reared on Ostrinia nubilalis and Spodoptera littoralis which were feed on corn leaves expressing Bt Cry1Ab had an increase mortality and delayed development; secondly, direct exposure of the lacewings to the Cry1Ab toxin in artificial diet had a toxic effect on the lacewings. Vojtech et al., (2005) did a series of laboratory studies looking at the tritrophic effects on the parasitiod Cortisia. marginventris. They looked at the survival, development and cocoon weights of C. marginventris reared on S. littoralis fed on both GM and non-GM food. Their study showed a significant negative effect on development time, survival and cocoon weight, for those C. marginventris reared on GM-fed S. littoralis. They also showed that this was an indirect effect as they could find no evidence of Bt accumulation in either the adult S. littoralis or the adult C. marginventris, (Vojtech et al., 2005).

While GM crops with pest protection traits are the most obvious to have non-target affects, other traits such as herbicide tolerance also could have non-target implications (figure 1.3). The concern with HT crops is that there is the potential to remove more weeds from a field than when using conventional crops and herbicides. The reason for this is the ability HT crops give the farmer to use broad

spectrum herbicides such as glyphosate and glufosinate. The impact the removal of weeds would have on farmland biodiversity was the subject of the Farm Scale Evaluations (FSE) in the UK (Firbank et al., 2003). The FSEs identified that GM HT crops do have the potential for eradicating weeds and therefore effecting non-targets indirectly through the food web. However they also identified that this was more a farm management issue then a GM specific issue, as intensive chemical herbicide applications or even over-enthusiastic organic hoers could remove all weeds and thus have a detrimental effect on biodiversity.

Figure 1.3: Representation of the potential non-target effects. Solid lines represent the direct effects and dashed lines represent indirect effects. The diagram includes the potential soil effects, these are specific to Bt which can be exuded into the soil via the roots and then has the potential to directly effect soil biota and functions.



There are also concerns over the non-target effects GM crops could have on the soil, (Saxena and Stotzky, 2000; Stotzky, 2000; USEPA, 2000). The concern is that with GM crops such as those expressing Bt resistance, the Bt toxins can be exuded from the roots into the soil (Carriere et al., 2001), where it can become stabilised by clay particles and humic acids (Stotzky, 2000), and remain active for hundreds of days (USEPA, 2000). Although Bt toxins are already found in the soil, as *Bacillus thuringenesis* is a soil-borne bacteria, crops' sources of Bt are likely to result in additional exposure of soil fauna to the toxins (Dale et al., 2002). There have been numerous tests carried out on soil invertebrates including earthworms and collembola. The only adverse effects observed have been when

exposure is over 500-1000 times greater then would be expected under normal field conditions (Zangerl et al., 2001).

It is quite apparent that GM crops could cause both indirect and direct effects on non-target organisms. This needs to be investigated, but in a way that is realistic to the field, rather then laboratory worst-case scenarios, in order to properly evaluate the environmental impacts. Tiered testing has an important role in the regulatory assessment of GM crops and enables a structured framework for worse case testing in the laboratory to be extended into large scale field trials through a number of tiered steps; for a comprehensive review see (Poppy, 2003; Raybould and Wilkinson, 2005). There is currently a lack of research looking into the non-target effects at a more regional or landscape level. This is something which will need to be addressed if proper predictions of risk are to be made (Belcher et al., 2005; Graef et al., 2005; Qvist et al., 2006; Shaw et al., 2006; Squire et al., 1999). The potential risk to non-targets needs to be seen in context of those risks posed by conventional methods as the risks needs to be properly evaluated. For example there is good evidence that the pesticide sprays used on maize may be more harmful to the Monarch butterfly than Bt corn pollen (Pimentel and Raven, 2000).

1.4.4 The potential implications for farm management practices

In recent history the green revolution has been the greatest advance in agricultural production (Conway, 2000). Increases in production were attributed to a number of factors: increased irrigation, intensive use of fertilisers as well as plant protection chemicals, the development of new crop varieties which responded better to high input systems (Peterson et al., 2000). However, it is now acknowledged that these advances came at a cost, and not only to the environment, but also to human health and well being. For example we have seen dramatic declines in many species of farmland bird and wild plant species, which we know to be associated with changes in farming practice over the last few decades (Fuller et al., 1995). The effects organochlorides have had upon birds of prey are a good example of this. It is however very difficult, in most cases, to tie

these declines to specific changes in agricultural production. Similar trends can be seen with plants and invertebrates (Donald, 1998).

Some now fear that the adoption of GM technology could also result in similar costs, brought about through altering how farms are managed, enabling farmers to further intensify and, in doing so, industrialising agriculture (Mannion, 1998; Matson et al., 1997). Indeed, any changes in agronomic practice associated with the introduction of a particular GM crop would have potential impacts on the environment (Dale et al., 2002). The major issue with GM crops that are already currently commercialised, in terms of potential to cause deleterious alterations to farm management practices, are two fold: firstly, they could result in the increased use of broad spectrum herbicides and secondly, they could result in the mass adoption of crops utilising one or two herbicides or pesticides, which may result in resistance.

1.4.4.1 The effects increased use of broad spectrum herbicides in conjunction with GM HT crops

The use of broad spectrum herbicides could result in a weed shift. Weed shift is a change in weed populations which reduces weed diversity and ecosystem complexity; in both the GM fields and on neighbouring farms (Dale et al., 2002). The argument is that because the GM HT crops currently available confer tolerance to broad spectrum herbicides glufosinate and glyphosate, their widespread use will reduce diversity of weeds in agricultural habitats. Radosevich et al., (1992) predicted that shifts in weed species composition and abundance would be exacerbated with the consecutive use of the same herbicide (providing favourable conditions for growth of a particular weeds, insects and diseases). Broadspectrum herbicides also give farmers the opportunity to have much cleaner fields then they might get with conventional crops which require the farmers to use a number of more specific herbicides. This was the initial concern which gave rise to the FSE in the UK (AEBC, 2001; Firbank et al., 2003), and as the FSE results showed it is a valid concern. A summary of the FSE results can be seen in table 1.4.

Table 1.4: Summary of the findings of the FSE taken from (Ammann, 2005)

Summary of the FSE Findings
Differences in biodiversity between crops exceed differences between GMHT and conventional crops (Champion et al., 2003; Haughton et al., 2003; Hawes et al., 2003; Heard et al., 2003; Roy et al., 2003) There were higher early season weed numbers and biomass in all three GMHT crops (Heard et al., 2003) and higher weed mortality in GMHT sugar beet and canola, resulting in lower late season biomass and seed rain of weeds in those crops, but lower weed mortality in GM maize (Heard et al., 2003; Peterson et al., 2000; Scientists Working Group on Biosafety, 1998). More detritivores (collembola) were observed in all three GMHT crops as a result of higher weed detritus (Brooks et al., 2003; Haughton et al., 2003). Lower numbers of bees, butterflies and Heteroptera in GMHT sugar beet and canola were observed as a result of reduced weed populations; generally higher numbers of invertebrates in GM maize, (Brooks et al., 2003; Wilson et al., 2004). Lower herbicide inputs required in GMHT crops (Champion et al., 2003). It has been argued that GM maize is performing better because it has been treated with the broad-band herbicide atrazine, but (Perry,2004), showed with a more detailed analysis of data from the trials that this is not the case: GM maize resulted in more weeds than conventional maize, even when treated with non-atrazine herbicides

While it is clear that GM HT crops do have the potential to alter weed biodiversity, the impact of the introduction will depend on the rotational and agronomic practices adopted to manage them (Dale et al., 2002). As Burnside (1996) and Altieri (2000), identified, the adoption of different herbicide use programs may have different effects on plant and animal biodiversity in fields and field margins. For further discussion on how the effects of changes in herbicide programs on plant and animal biodiversity in field and field margins have being investigated in the UK see Sweet and Shepperson (1997) and the FSE papers (Brooks et al., 2003; Champion et al., 2003; Firbank et al., 2003; Haughton et al., 2003; Hawes et al., 2003; Heard et al., 2003; Perry et al., 2003; Roy et al., 2003; Squire et al., 2003).

1.4.4.2 The utilisation of one or two crop traits resulting in resistance development

One of the most widely discussed issues when it comes to potential alterations GM will cause in farm management, is whether the adoption of one or two trait will result in the development of resistance (Monjardino et al., 2005; Owen and Zelaya, 2005). In conventional agricultural there is a long history of the development of resistance, especially if one or two crops, or pesticides, are used consistently over a period of time, as it increases the selection pressure for resistant individuals. Herbicide tolerance is more likely to evolve from selection

pressure due to poor agricultural management than it is from gene flow of a resistant gene (Moyes et al., 2002; Senior and Dale, 2002). In terms of resistance there are already a number of examples of species which are tolerant to glyphosate use in conventional agriculture: ryegrass in Australia, (Pratley et al., 1996) and horseweed in the United States (VanGessel, 2001). With widespread utilisation of GM HT crops more are to be expected. In terms of resistance to pest protection crops, for example Bt, there are several laboratory studies which have shown resistance can be selected for (Shelton et al., 2002); however, there are yet to be any field examples. Interestingly, there are examples of resistance to the biopesticide Bt spray (Alstad and Andow, 1995).

The issue with the acquisition of resistance, to Bt or broad spectrum herbicides like glyphosate, due to poor management, is that both glyphosate and especially Bt (as a biopesticide) are considered to be environmental beneficial (Dale et al., 2002). If resistance to them develops the fear is that farmers will resort to using larger doses or less environmentally benign substitutes to quash resistance. There are a number of strategies which are being used in an attempt to manage resistance, especially in insect pests (Alstad and Andow, 1995; Monjardino et al., 2005). The high-dose refugia strategy which has been implemented in North America has been more successful then many anticipated (Alstad and Andow, 1995), even with almost 30% of the farmers in the year 2000 failing to comply with the refuge protocols designed to prevent or delay the emergence of insect resistance to Bt toxins (Dove, 2001). Companies are now developing varieties which are resistant to a number of herbicides or have a number of insecticidal genes incorporated; this is commonly known as the "pyramid strategy". By incorporating a number of insecticidal genes or enabling the crop to be tolerant to a several of herbicides, it will make it harder for resistance to evolve (Manyangarirwa et al., 2006; Roush, 1998; Witcombe and Hash, 2000).

Although there are real concerns about the implication the adoption of GM will have on farm management practice, there is also a need to see this in the context of all agricultural change. As we have already seen changes in agricultural

practice such as changes in sowing time have had dramatic effects on farmland and wider environmental biodiversity (Huusela-Veistola et al., 2006; Ozturk et al., 2006; Rinaldi and Vonella, 2006; Vocanson et al., 2006).

1.4.5 Summary

"*Human exploitation of the environment, in all forms, has altered and continues to alter the resulting balances, producing changes that cascade far beyond the directly affected sites and extend to biodiversity, human well-being and even the global climate*" (Scientists Working Group on Biosafety, 1998). Agriculture itself creates change; if land was no longer managed for agriculture the environment would change, the landscape would go back to temperate forests and as a result the composition of species would alter swaying towards those which thrive in forest conditions. Alterations to agriculture in turn make smaller changes; these have already been demonstrated in conventional agricultural production. GM, too, could and will bring about change: changes to the environment and changes in the potential risks agricultural production heralds. What needs to be considered, when discussing the potential changes introduced by GM crop commercialisation, is whether some of these questions should also be asked about conventionally bred crops, and if they should not, why we are asking them about GM crops.

The extent and gravity of these risks have to be assessed, however they also need to be placed in context. As without context all change is unacceptable; placed within context the extent of the change begins to gain perspective. The context within which GM needs to be placed is three fold: firstly, the environmental risks of GM crops need to be compared to the risks associated with its comparators, secondly, the risks of GM crops need to be considered in the context of the benefits and finally, the potential risks of adopting a GM technology should also be considered alongside the risks of rejecting the technology and this should be done on an environmental, economic, political, ethical and social level. Numerous authors have drawn the same conclusions when discussing, evaluating and analysing the risks (Beringer, 2000; Dale et al., 2002; Ervin et al., 2003; Peterson et al., 2000; Uzogara, 2000a)

1.5 The current regulatory process governing the deliberate release of GM crops

Because of the associated risks, GM technology, especially crops, should be regulated in order to ensure the safety and wellbeing of both the environment and human health as well as to maintain confidence in the technology. The regulation, however, should not act as a barrier to innovation or a specific technology (Tait and Williams, 1999). Jaffe, (2004), identifying that there are many reasons why the government regulates and oversees processes and products, (table 1.5). These are not just the obvious, to ensure safety both for human health and the environment, but also to ensure public protection in other ways: to protect cultural, ethical and society choice or values, to negate societal concerns, and to implement international obligations.

Table 1.5: An overview of the reasoning behind regulating a product or process adapted from (Jaffe, 2004)

"To ensure human safety" – Governments across the globe regulate a number of products to ensure human health, for instance the regulation of the pharmaceutical industry.
"To protect the environment" – A number of governments have put in place environmental regulations to ensure environmental protection, for instance regulations to limit environmental pollution.
"To protect against fraud" – A number of governments require labelling on food products, so as not to mislead consumers. Seed varieties are also regulated in this way.
"For societal and ethical reasons" – To ensure ethical and societal values are met, for instance the use of animals in scientific research is heavily regulated to ensure they are humanely treated.
"Because of public concern" – Often governments regulate a product or process to negate public concerns, ideally providing the public with confidence in the product or process.
"To comply with international obligations" – there is a number of international legislations and treaties governments have signed up to, like the Cartagena Biosafety Process, which they are obligated to bring into regulations for compliance.

Governments, and essentially society, regulate to provide the public with the confidence that a new product is not harmful to either them or the environment upon which they depend. GM is a new technology and potentially encompasses a range of novel risks, to human health (Malarkey, 2003; Scientists Working Group

on Biosafety, 1998; Uzogara, 2000b), the environment (Conner et al., 2003; Falk et al., 2002b; Snow et al., 2005; Weaver and Morris, 2005), and more broadly society at large (Annerberg, 2003; Gaskell, 2004c; Hollander, 2002; Madsen et al., 2003a; Walls et al., 2005). There are also a number of scientific uncertainties associated with GM crops and the transformation process required to develop them (Eden, 1998; Levidow, 2001; Schenkelaars, 2001). Irrespective of the scientific concerns, or lack of concerns, there is clearly a public unease associated with GM technology (Andree, 2002; Annerberg, 2003; Crane et al., 2006; Halford and Shewry, 2000; Miles et al., 2005). This unease is particularly apparent in relation to food products and agriculture (Wu, 2004), and need to be addressed in order to assure the public.

The big question then is not whether there is a need for the current regulatory system to govern the deliberate release of GMOs, but whether the current system fulfils the requirements set out above. I would argue, when discussing the European regulatory system, that in some areas it far exceeds what is required from it; however in others, it falls very short. This extends to most regulatory processes governing the deliberate release of GM crops globally. The current regulatory process in Europe will be discussed below, including its origins, the scope of what is required from an application for deliberate release, as well as the process an application goes through under review, before it is passed for release. Then a number of other regulatory processes will be considered in brief and compared and contrasted to the regulatory system in Europe. These will include the American and Canadian systems.

1.5.1 The European Union regulatory process

Within the EU's legal framework: a Regulation is a law that all Member States should eventually adopt into their local laws by passing through their individual parliaments; and a Directive is a minimal set of demands which should be interpreted and implemented in the national legislation of the Member State (Nap et al., 2003)

In 1990 the EU implemented the first two Directives legislating over GM crops, these were Directives 90/219/EEC which involved the contained use of GM (micro)organisms and Directive 90/220/EEC which involved the deliberate release of GM organisms including plants into the environment (Council of the European Commission, 1990a; Council of the European Commission, 1990b). As this study focuses on GM crops only 90/220/EEC will be considered in further detail. Directive 90/220/EC distinguishes two categories for environmental release, Part B and Part C. Part B is generally applied to the release of GM crops for conducting field experiments within a Member State. As such they are filed and granted on a national level by the Member State concerned. Part C, is applied to releases intending to place GM crops on the commercial market, as such they are considered at the European level, with all Member States being involved in the regulatory process, as once issued, the release is applied across all Member States. A summary of the notification procedure for Part B and C release can be seen in table 1.6.

Table 1.6: An overview of the process for Part B and C releases in accordance with Directive 90/220/EC and later Directive 2001/18/EC. Taken and adapted form The AEBC 2001 report Crops on Trial (AEBC, 2001).

Part B Releases Applicants must submit a detailed notification (for the intention of release) dossier, the requirements of which are stipulated in Annex 3, to the relevant competent authority of a Member State (who in the UK is DEFRA, formerly DETR). The decision about release is made by the individual Member State to which the release has been notified. The Member States decision should be *"solely on the basis of safety to human health and the environment"*. If permission is given then it applies solely to the locations stipulated in the notification dossier, and in addition conditions for release can be imposed.
Part C Releases Applicants initially submit a detailed notification dossier to the relevant competent authority of a single Member State, for initial approval. The Member State selected becomes the lead Member State, and thus takes the lead in the evaluation of the dossier. As well as including a detail risk assessment (requirements for which are in Annex 3), it also includes: extended information taking into account the diversity of sites of use of the product including information gained from research and developmental releases carried out under Part B consents; information concerning the ecosystems what that could be affected by the use of the product and an assessment of the risks posed to human health and the environment; conditions for placing the GMO on the market including conditions for use and handling a proposal for labelling and packaging. After the initial review of the dossier by the lead Member State, if the dossier is not rejected then the competent authority will submit the dossier to the European Commission with a favourable opinion. The Commission will then circulate the dossier to the other Member States, which all

evaluate it. This is to enable them to "*take into account the particular health and environmental safety issues unique to their territories*". If one or more Member States objects the Commission will seek the opinion of, initially the Scientific Committee on Plants, later the European Food Safety Authority (EFSA).
If the Commission deems that approval should be granted it calls upon the Member States to vote, the vote is based on a qualified majority. If the Member States do not reach a qualified majority either way the vote is referred to the Council of Ministers, who also needs a qualified majority. If there is not a qualified majority at either stage the vote is referred back to the Commission, who often base their decision upon the advice given by EFSA.

If the application is approved then it is up to the lead Member State to set provision for the release. There is also the power for Member States under Article 16, (discussed in more detail below), to restrict use or sale on a provisional basis if the Member State feels in light of new scientific evidence their opinion towards the risk assessment changes in terms of concerns over the safety of the product.

Central to 90/220/EC is the view that, "*GM is considered something new and special for which existing legislations are not sufficient*", (Nap et al., 2003); the result of this is the regulatory system in the EU which is a process-driven rather then a product-based (Gaskell, 2004c; Guehlstorf and Hallstrom, 2005), as it is in other countries (section 1.5.3).

Directive 90/220/EEC lacked provisions for the use of GMOs for food purposes, therefore Regulation (EC) No. 258/97 was drawn up, for "*the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the community*" (Arvanitoyannis et al., 2006).In 2001, Directive 90/220/EEC was replaced by Directive 2001/18/EC, which came into force in October of 2002 (Council of the European Commission, 2001b). This was largely driven by the 1999 *de facto* moratorium (Lieberman and Gray, 2006), on the commercial licensing of new GM products in Europe. The moratorium was borne out of a movement, in the late 1990s, away from the concept of "Substantial Equivalence", towards a more precautionary approach symbolised by the "Precautionary Principle", (table 1.7). Essentially this was effectively moving from the stance '*innocent until proven guilty*' to '*guilty until proven innocent*', (Lieberman and Gray, 2006).

Table 1.7: Defining Substantial Equivalence and the Precautionary Principle

Substantial Equivalence – a principle which emerged out of the need for regulatory oversight of

biotechnology and was used primarily by the Organisation for Economic Cooperation and Development OECD)/ Food and Agriculture Organisation (FAO) as a form of bench mark with which they can assess the food safety of GM. In a statement by the FAO, "*The OECS has... ...advocated that the concept of substantial equivalence is the most practical approach to address the safety evaluation of food or food components derived by modern biotechnology. Substantial equivalence embodies the concept that if a new food, or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety*" (FAO, 1996).

Precautionary Principle – "*the precautionary principle may be invoked when the potentially dangerous effect of a phenomenon, product or process have been identified by a scientific and objective evaluation, and this evaluation does not allow the risk to be determined with sufficient certainty... ...the precautionary principle may only be invoked when the three preliminary conditions are met – identification of potentially adverse effects, evaluation of the scientific data available and the extent of scientific uncertainty*" (Europa, 2000).

The first real indication of a move towards a precautionary approach was in February 1997, when Austria invoked the 'safeguard measure' incorporated into Article 16 of Directive 90/220. Article 16 is the so called safeguard clause, "*Where a Member State has justifiable reason to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or the sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision*" (Directive 90/220/EC); this enabled Member States to ban a GM product that has been approved by the EU. The Austrian ban was invoked against Novartis, Bt 176 maize variety; this was promptly followed by Germany and Italy invoking safeguard causes, (table 1.8), although it should be noted that a number of member States enacted safeguard clauses prior to the Austrian enactment.

Table 1.8: Safeguard clauses invoked around the time of the moratorium (Lieberman and Gray, 2006)

Year	Member State	Crop Variety
1997	Luxemburg	Maize
1998	Greece	Oilseed rape
1998	France	Oilseed rape
1999	Austria	Maize (2 varieties)
2000	Germany	Maize
2000	Italy	Maize (4 varieties)

A European Commission vote was held on whether Austria and Luxemburg should be asked to repeal their bans. The vote was split, indicating a negative shift in the Member States' opinions of the technology (Lieberman and Gray, 2006). At the same time a Commission proposal to amend Directive 90/220 so that it would reflect the concerns of the Member States (Europa 2004) was brought forward. Underlying this proposal was a declaration, dubbed 'the French Position', signed by four other Member States: Denmark, Greece, Italy and Luxemburg. The position identified, "*the importance of the Commission submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO derived products and state that pending the adoption of such rules, in accordance with preventative and precautionary principles, they will take steps to have any new authorisations for growing and placing on the market suspended*", (Marris, 2000). The fact that the French position was supported by four other Member States meant that there was enough support to achieve a blocking minority and therefore a *de facto* moratorium. The proposal from the Commission was put in front of the European Council of Environment Ministers in June 1999. The council agreed, "*to tighten up several aspects of the original proposal: the ethical dimensions and precautionary principle were taken into account, products containing GMOs would have to be clearly labelled and the possibility of exempting products with a GMO content below a certain threshold from the labelling obligation was added. A maximum validity of 10 years was set for the initial consent to place a product on the market, accompanied by provisions on monitoring, labelling and mandatory consultations of the public concerning GMOs*" (EU, 1999). Directive

2001/18/EC was adopted in February of 2001 and officially came into force by October 2002. In accordance with Directive 2001/18/EC the laws, regulations and administrative provisions of the Member States should be approximated and human health and the environment should be protected when carrying out any deliberate release into the environment of GMOs for any other purpose than placing them on the market within the community, or placing on the market GMOs as or in products within the Community.

The Directive is considered to present a "*substantially revised version of the previous directives*" (AEBC, 2001; Jaffe, 2004). The major philosophical shift (as already discussed) involved the use of the precautionary principle as a guide, as opposed to adopting the concepts of Substantial Equivalence (and Familiarity- addressing the same principle but applied to food production). In adopting a Precautionary approach the Directive requires the evaluation of both the direct and indirect effects, the immediate and delayed effects of commercializing GM varieties (Conner et al., 2003; Nap et al., 2003). Marketing the crops will also be conditional upon post-marketing surveillance, which gives the competent authority the right to conduct inspections and compliance measures. It also enables Member States to restrict or prohibit use of an approved GMO if new or additional information provides, "*detailed grounds for considering that a GMO... constitutes a risk to human health and/or the environment*" (Jaffe, 2004). Prior to 2001/18/EC restriction of use was only on a provisional basis (AEBC, 2001). The ability to trace a GMO at all stages to market was also made a requirement of 2001/18/EC. The Directive called for the phasing out of genes encoding resistance to antibiotic, by 2005 for commercial release and by 2009 for research purposes; such genes were used as marker genes were used as markers in medical and veterinary treatment. Finally the Directive has a provision which states that, "*Member States may take into consideration ethical aspects*" when reviewing GMOs (Jaffe, 2004); although some would still question whether Member States make full use of this (see section 1.6).

Since Directive 2001/18 came into force in October 2002 there have been a series of amendments made, as well as new regulations attached to it. Table 1.2 in appendix one, summarises the Directive, and its amendments as well as a number of additional regulations that have come into force since them. The additional regulations are concerned primarily with the traceability and labelling of GMOs plus food and feed products produced from GMOs, a particular issue stated in the 'French Position' and part of the reason that the Commissions decided to revise Directive 90/220.

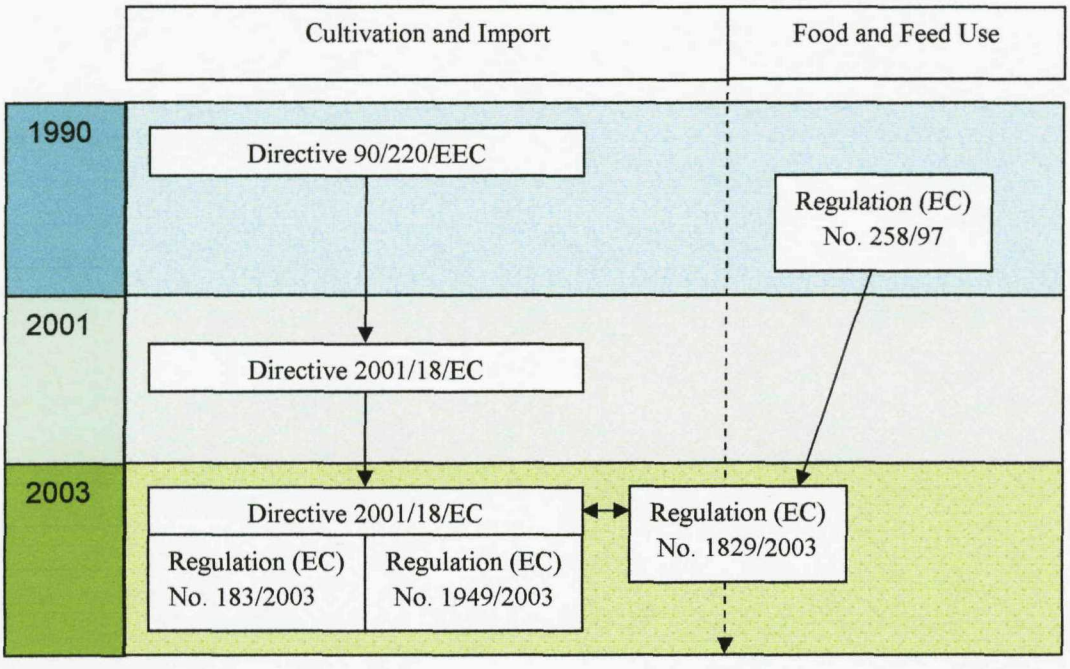
Directive 2001/18 has improved the regulatory procedure for GM crops in a number of ways: it has tightened up the process, in terms of what is required from the risk assessment, and changes how Member States interpret the Directive into their own national legislation. Prior to 2001/18 there had been huge differences in the way 90/220/EEC had been implemented between Member States, which resulted in confusion and disparities (Nap et al., 2003).

With Directive 90/220/EEC being repealed by Directive 2001/18/EC, the Food Regulation, Regulation (EC) No. 258/97, also needed to be replaced. In March 2003 Regulation (EC) No. 1829/2003, commonly termed 'the Food and Feed Regulation' entered into force. The new component introduced by the Food and Feed Regulation is a centralised authorisation procedure for GMOs used as food or feed for animals, meaning that those wishing to market GM crops in the EU need not request separate authorisation for both uses or for either (Nuffied Council on Bioethics, 2004). Thus whereas Directive 2001/18/EC could only give consent for applications to import and cultivate crops, Regulation (EC) No.1829/2003 covers the use of GMOs in both food and feedstocks. Indeed authorization for deliberate release for cultivation (if the GMO is envisaged as a potential food or feed product) can be sought under Regulation (EC) 1829/2003 as this works in accordance to the criteria laid down by Directive 2001/18/EC; applications can also be submitted under, Directive 2001/18/EC and Regulation (EC) No. 1829/2003. A comparison of Directive 2001/18/EC and the Food and Feed Regulation 1829/2003 can be seen in appendix one table 1. 3.

There are two big changes brought in by the Food and Feed regulation: firstly, the use of GMOs in animal feed previously did not require a specific authorisation procedure (Nuffied Council on Bioethics, 2004); secondly, applications for release now go through a centralised authorisation procedure, because all applications now go directly to EFSA (EFSA, 2004), (table 1.4 appendix one), rather then to a lead Member State as was the case under Directive 2001/18/EC.

The EFSA GMO panel website (EFSA, 2007b) makes all the information publicly available to those who are interested (barring that which is commercially sensitive). It holds all the information about the panel members and working groups, provides the details of all the applications which have been submitted under the Food and Feed Regulation and produces a summary of each notification dossier and of all the EFSA opinions and guidance given. The EU regulatory process legislating the release of GMO is a highly complex and multifaceted process. Figure 1.4 illustrates how the numerous facets of the GM legislation in Europe interact.

Figure 1.4: Timeline of EU regulations and their roles in regulating the cultivation and import of GMOs and the use of GMOs in Food and Feed products.



1.5.2 International legislation

Legislation for the deliberate release of GM crops exists at many levels: national, regional through to international level. Certainly national policies are heavily influenced by international regimes and to a certain extent vice versa. As the Nuffield Bioethics report (2004) suggests, "*all countries face the challenge of ensuring that policies towards GM crops make sense in the context of their own development needs, and also that they cohere with the complex system of international governance that is developing for GM crops*". This section will briefly introduce some of the key pieces of international governance that influence the EU regulatory system. There are four pieces of international regulation which relate to GM crop, research, trade and use, these are:

- Agreements by the World Trade Organisation (WTO)
- The *Codex Alimentarius*
- The Cartagena Protocol on Biosafety
- The International Treaty on Plant Genetic Resources for Food and Agriculture

All four influence EU regulations, and are discussed in more detail in appendix one, table 1.5.

1.5.3 Comparable international processes

The EU regulatory process needs to be considered in an international context. In this section both the American and Canadian regulatory processes will be considered. Both contrast strongly with the European System mainly due to their product based approach to regulating GM crops and products derived from them (Conner et al., 2003; Ervin et al., 2003; Guehlstorf and Hallstrom, 2005; Jaffe, 2004; Nap et al., 2003). For more information about other regulatory processes refer to (Barrett et al., 2001; Ervin et al., 2003; Jaffe, 2004; Nap et al., 2003) or refer to their websites compiled in table 1.6 appendix one adapted from Singh *et al* (2006).

1.5.3.1 The regulatory procedure for the deliberate release of GMO in the United States of America (USA)

The USA system is the oldest and most experienced in the world (Jaffe, 2004); for a comprehensive overview refer to Byrne *et al*, (2002) . In 1986 the Co-ordinated Framework for Regulation (CFR) of Biotechnology specified that the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) along with the Environmental Protection Agency (EPA) and the Food and Drug Agency (FDA) would be the primary governmental bodies for regulating biotechnology in the USA (refer to table 1.7 appendix one for an overview of their roles), and the CFR is still in use today (MacKenzie, 2000).

The central, and some would say crucial (Nap et al., 2003), decision made by the CFR in relation to the regulation of GM crops was that no new and specific biotechnology regulation system would be necessary for their legislation (MacKenzie, 2000). Unlike the EU process which saw GM technology as novel and therefore in need of new regulations, the CFR saw GM crops as posing no novel risks. Thus the CFR deemed the current legislation: the Federal Plant Pest Act, the Federal Plant Quarantine Act, and the Federal Insecticide Fungicide and Rodenticide acts to be adequate. These made the USA regulatory process a

product-based assessment, rather then a process-based assessment as used in the EU. It is this difference, which is a result of two very different philosophical approaches, which has sparked much controversy over the recent years. A comparison of the two regulatory processes taken from Jaffe (2004) is presented in table 1.9.

Table 1.9: A comparison of the USA and EU regulatory process taken from Jaffe (2004)

Country	**United States of America**	**European Union**
Use of existing legislation	Yes	No
New legislation and or regulations	New regulations only	Yes
Statutes involved	Plant Protection Act Federal Insecticide, Fungicide and Rodenticide Act Federal Food Drug and Cosmetics Act	EU Directive 2001/18/EC Regulations 183/2003; 1949/2003; 1829/2003
Agencies involved	USDA FDA EPA	Member State's Competent Authorities European Food Safety Authority European Commission
Crops covered	Plants that could become a plant pest Plants engineered to produce a pesticides Plants intended as food	All genetically modified organisms All novel foods and novel food ingredients
Activities covered	All releases into the environment (field trials and commercial products) Foods derived from transgenic crops	Releases into the environment and placing a GMO in the market as or in products
Mandatory pre-market approval	Yes for the environmental review No for the food safety review	Yes
Established safety standard in legislation	Yes	Yes

A report by the National Academy of Sciences (NAS), evaluating the current USA regulations (NAS, 2002), suggested that tighter monitoring of the environmental releases of all crops, including those resulting from traditional breeding, is necessary. This has been echoed in a USA scientific assessment by the National Research Council (NRC) which concluded that "*some of the risks posed by transgenic crops are unique and that the regulatory system has not been functioning effectively*" (NRC, 2002). One of the main criticisms by both reports was the reliance on principles such as "Substantial Equivalence" and "Familiarity"; as these assume that the genetic modification is precise, in that the single gene modification does not significantly alter the other plant processes (Ervin et al., 2003). Interestingly there have been moves toward a more process based regulatory system in the USA with the reissuing of EPA regulations in 2001, following recommendations from the NAS (National Academy of Science, 2000a).

1.5.3.2 The regulatory procedure for the deliberate release of GMO in Canada

The Canadian government approaches the regulation of biotechnology products in the same way it would any new technology or product line, from a safety-based and science-based approach (Macdonald and Yarrow, 2003). The framework was approved by the Canadian Government in 1993 and was also born out of growing environmental concerns over the use of GMO (Macdonald and Yarrow, 2003), although it dealt with the impacts of biotechnology on other commodities, as well as the environment, such as fertilisers, livestock feeds, processed foods and veterinary vaccines. The main aim for developing the Framework was to steer the Federal Regulatory Approach. The Framework achieved this by the formation of an agreement among the Federal Regulatory Departments and Agencies to follow six key principles (Finstad et al., 2007):

1. To maintain Canada's high standards for the protecting of the health of workers, the general public and the environment
2. To use existing legislation and regulatory institutions to clarify responsibilities and avoid duplications

3. To continue to develop clear guidelines for evaluating products of biotechnology which are in harmony with national priorities and international standards
4. To provide for a sound scientific baseline on which to asses risk and evaluate products
5. To ensure both the development and enforcement of Canadian biotechnology regulations in an open and consultative manner
6. To contribute to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes

Fundamental to the framework's approach is the use of existing legislation and institutions, (point two in the framework), rather then the production of "gene acts" and "biotechnology agencies" (Macdonald and Yarrow, 2003), making the Canadian approach more inline with the USA approach rather then the European one.

The Canadian regulatory process, in terms of its legislation, takes a product-based approach, similar to the US system, in that it is concerned with the novelty of the trait rather then the novelty of the production process. It differs dramatically from the US in terms of what is covered by this approach, as the Canadian process is concerned with "*novel traits in the Canadian environment in general, and not just plants with novel traits modified through recombinant DNA techniques*" (Macdonald and Yarrow, 2003). The Canadian regulatory process states a plant with a novel trait (PNT) "*may be a product of recombinant DNA techniques, mutagenesis, or even conventional breeding, providing that a trait has been introduced that is both new to Canadian populations of that species and has the potential to have significant environmental impact*" (Finstad et al., 2007). This novel product based approach included multi-stakeholder consultations prior to assuming the regulatory responsibility. The consultations were carried out in conjunction with the Canadian Agricultural Research Council (CARC), a consortium of researchers from academia, industry and government. The CARC

identified the need for "*an environmental safety assessment to exist regardless of whether the introduction of novel traits is achieved through mutagenesis and selective breeding of new genetic engineering techniques*" (Macdonald and Yarrow, 2003).

There are two Federal Agencies responsible for regulation of PNT: Health Canada who assess the food safety of PNTs, and the Canadian Food Inspection Agency (CFIA) whose Plant Biosafety Office (PBO) are responsible for assessing the environmental safety assessment as well as the livestock feed safety. These agencies work under the authority of Part V of the Seed Regulations. The PBO can approve releases at two levels, (similar to EU Directive 2001/18): confined research field trials (similar to Part B releases) and unconfined environmental releases (similar to Part C releases). The process of authorisation for confined and unconfined environmental releases is outlined in appendix one table 1.8, adapted from Finstad et al., (2007).

There have been a number of calls made to those who are in charge of regulating GMOs in Europe to look towards the Canadian system as a more suitable approach to the regulation of GMOs (Barrett et al., 2001; Morris, 2006). More recently, in a report made by the UK Advisory Committee on Releases to the Environment (ACRE) entitled "Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems"(ACRE, 2007a), there was the suggestion that, "*the Canadian approach was an example of a model worth considering, which would avoid or minimise some of the anomalies of the current (EU) system*". One of the main concerns is that GM crops are regulated when other methods that could produce novel traits equally environmentally detrimental are not; an example would be herbicide tolerance (HT) crops. HT GM varieties are regulated in the UK whereas HT non-GM varieties such as BASF Clearfield are not, however both pose similar environmental risks when considering weedy characteristics, and indirect non-target effects. Inconsistencies between the regulation of the two is a clear cause for concern for some (ACRE, 2006; Barrett et al., 2001; Morris, 2006; Peterson

and Sharma, 2005). In Morris (2006) paper, "EU biotech crop regulations and environmental risks: a case of the emperors new clothes?" this issue is covered in depth.

1.5.4 Summary

For a regulatory system to be a success it clearly does not only have to protect human health by making sure only crops that are safe to eat are put on the market, but also needs to ensuring that transgenic crops pose negligible risks to the environment. A successful regulatory system also has to inspire public confidence, as the public will need to have confidence in its results, in terms of risk determinations, if they are to embrace the safety of those products going through it. This is a sentiment echoed by Jaffe (2004), "*if a successful regulatory system is put in place, human health will be protected because only products that are safe to eat will be marketed. Similarly, the environment will be protected if the environmental risks for each transgenic crop are properly analysed before it is released into the environment and those risks are either minimised or effectively managed prior to release. Then consumers will trust the regulatory process, have confidence in the resulting safety determinations, and embrace those safe products*". The question is, does the public have confidence in the regulatory system that governs the deliberate release of GM organisms? This question is addressed in the following section.

1.6 The societal debate surrounding GM crops

Society is becoming increasingly risk aware, to the extent that some social scientists deem that we are now living in a 'risk society' (Beck, 1992). A risk society is a natural development from an industrial society, one which "*has produced an enormous amount of goods and a society of material affluence; it has also produced new risks and new dangers. The modern risks are the unwanted by-products of modern capitalism and industrialism*" (Elkstrom and Askegaard, 2000). Eventually as risks mount, modernity is considered to reach a tipping point and develops into a (reflexive or) risk society (Knight, 2007). A risk society starts to evolve when "*the gains from the technological progress that society is making*

are increasingly being overshadowed by the production of risks"(Beck, 1992). A resultant of a risk society is that people start to question previously taken for granted premises and institutions (Beck et al., 2003); and to an extent this is what is happening in the EU with agriculture and in particular agricultural biotechnology.

In Europe, certainly in terms of the use of biotechnology to progress agricultural production, the effect of becoming a risk society are overtly apparent (Durrant et al., 1998; Gaskell, 2004a; Gaskell, 2004c). A common feature of new technologies always has been a relatively slow initial uptake and acceptance; an example of this is the first vaccination against smallpox (Braun, 2002). New technologies, like biotechnology, influence society's economic and political structures; as such it often raises issues relating to core societal values (Frewer et al., 2004; Keller, 2007). In Europe over the last decade there has been a remarkable rise in public concern covering a wide range of new technologies (Munnichs, 2004) and much of this societal pressure is starting to influence scientific innovation. For example increasing levels of openness and transparency has come about as a result of controversies surrounding the impacts new technology may have in modern society (Mayer, 2003).

There have been several notable examples in Europe when scientific innovations have impacted society, a number of which have resulted in food or health scares as well as having environmental implications. Scares surrounding BSE (bovine spongiform encephalopathy), dioxins in dairy products, DDT and more recently the deliberate release of GM crops, are just a few examples that justify societal concerns with new technologies. The major concern society has with new technologies is their ability to render existing governmental and regulatory procedures obsolete (Keller, 2007), "*as it is in the nature of fast-moving scientific research that its progress can outstrip the ability of its lines of social, ethical and regulatory support to keep up*" (Salter and Jones, 2002).

While new technology often greatly influences society, society also influences new technology. "*The way society structures its policies and institutions for supporting regulating and judging the safety of technologies has a strong influence on the pace and direction of their development*" (Keller, 2007). In fact "*public perceptions and attitudes about emerging biosciences and other new technologies are among the most important factors determining the likelihood of the successful development and implementation of technology*" (Frewer, 2003). Consumers' shopping behaviour and political regulations will determine how the technological advances of biotechnology will be used in the future (Siegrist, 2000). This has already been demonstrated with the removal of GM products from their shelves by supermarkets in Britain (Gaskell, 2004c; Pidgeon et al., 2005; Poortinga and Pidgeon, 2006). It is not just product development which will be dictated by consumers' attitudes, many scientists are aware that the attitudes the public have will strongly impact upon the progress, support and funding for their field of research (Rabino, 1994). The disruption of field trials in the UK and the resulting withdrawal of industrial research facilities from the UK and Europe, is a prime example of how scientific research can and is affected directly by societal attitudes (Gaskell, 2004c); adoption of the technology in developing countries is also affected by consumer and political attitudes in Europe. Firstly, Developing Nations risk losing an export market if they grow GM crops (Poortinga and Pidgeon, 2005); secondly, some countries look to attitudes in other developed countries to help form their own. The effect of this has been seen with the turning away of GM food aid from the US by Zimbabwe and Mozambique in 2002 (Wu, 2004).

The complex interactions between a technology and a society to which it is to be introduced (Guston, 2000) needs to be better understood, "*as public's attitudes have been identified as one of the key determinants of the development, application and subsequent technological evolution of technology*" (Advisory Committee on Science and Technology, 1990). Without societal support for a technology, it is unlikely to be adopted; as identified by the European Commission (Council of the European Commission, 2002), "*without broad public acceptance and support, the developments and use of life science and biotechnology in*

Europe will be contentious, benefits will be delayed and competitiveness will be likely to suffer".

1.6.1 Surveys as a measure of public opinion

Many opinion surveys have been conducted in Europe and elsewhere which have attempted to identify consumers' responses to GM products (Frewer, 2003). There are some methodological concerns, especially in relation to comparisons between surveys, low response rates, and self selection (Campbell and Townsend, 2003; Townsend and Campbell, 2004); however they do give insights into public opinion.

1.6.1.1 European surveys of public attitude

The most extensive survey of opinion in Europe has been the Eurobarometer surveys. They have monitored changes in public attitude towards biotechnology in the different European Member States since the early 1990s (Council of the European Commission, 1997) gauging a series of attitudinal measures towards science in general, and biotechnology more specifically. In general, Europeans had a positive view of science and technology but no longer regard scientific advances as a universal panacea for all problems (Frewer, 2003). Consumer attitudes towards GMO were more negative; in particular their concerns over consumer choice, and the potential negative effects deliberate releases could have on the environment. For example when asked to rate their support for several new technologies, in terms of whether it would improve our way of life, 39.73% of Europeans rating biotechnology as improving our way of life. This came way under solar technology (73.54%), computers (78.22%), telecom (80.69%), new materials (63.26%) and space exploration (49.82%). Meanwhile, the public distinguished between different applications of biotechnology: perceptions of risk was greater for biotechnology in food compared with other areas of biotechnology (Marchant, 2001), such as medical applications. The Eurobarometer also identified that Europeans' perceived a lack in their knowledge of biotechnology, with around 80% of respondents (in the 1999 Eurobarometer) stating they were insufficiently informed about biotechnology (Gaskell et al., 2000). It should

however be noted that there are clear socio-demographic difference in consumer attitudes (Council of the European Commission, 2001a), thus consumers are not homologous concerning their attitudes toward GMO. Public attitude has become increasingly negative towards biotechnology over the years the Eurobarometer has been conducted (Frewer et al., 2004).

1.6.1.2 Surveys of public opinion on a National level

Numerous surveys about public attitudes towards biotechnology have been carried out on a national level within the European Member States, including several Mori Polls (MORI, 2004), numerous Eurobarometres (Council of the European Commission, 2001a), independent surveys by public researchers and the private sector(Madsen et al., 2003b; Pidgeon et al., 2005). These have all demonstrated the range of public opinion in Europe, within and between Member States, towards GM crops. In 2003, in the UK, the government engaged in a stakeholder participation event, entitled the "GM Nation? Public Debate". It was a "*major multistage deliberative exercise assessing the UK's public attitudes towards the commercialization of agricultural biotechnology*" (Pidgeon et al., 2005). The results of the open GM Nation debate would suggest that the UK public were highly sceptical of GM, the majority agreeing with questions stating concerns about the technology and disagreeing with any statements identifying potential benefits. There are a number of questions about the methodology used (Horlick-Jones et al., 2004) not least because the sample were somewhat self-selecting, with the exception of the narrow-but-deep focus groups. A MORI survey was also commissioned at the same time, which was made up from a nationally representative quota, which drew similar finding in terms of a majority of respondents agreeing with questions stating concerns about the technology; but when it came to statements identifying benefits, a majority also agreed with these, although to a lesser extent. This suggested that while the UK public strongly identified with the potential risks of GM technology, they could also identify its potential benefits. In comparing the results from the two surveys, Pidgeon et al., (2005) concluded "*the individuals who attended the open GM Nation? activities were not duly representative of the underlying British population in terms of their attitudes to the potential benefits*". A number of other studies have also cast doubt

on the findings of the GM Nation, that the British public are implacably opposed to GM food and crops (Grove-White et al., 1997; Marris et al., 2001; Poortinga and Pidgeon, 2006).

1.6.1.3 Surveys of public perception outside of Europe

Comparisons using Eurobarometers between Europe and other countries (Japan, New Zealand and Canada) have been made in the past (Macer, 2005). Broad differences between countries' attitudes were observed, New Zealanders tend to be more positive about agricultural applications and Canadians are most convinced by the adequacy of their regulatory practices. Both New Zealanders and Europeans expressed concerns about the adequacy of their risk management regulations (Macer et al., 1997). The attitudes of the public in the USA is probably considered to be most different to those of Europe, as most opinion polls indicate that genetically modified foods have failed to make a significant impression on the public's consciousness in the US (Beckwith et al., 2003), although a survey by Priest (2000) suggest that acceptability of GMO by the American public is more equivocal then some would expect.

1.6.1.4 The surveys account of public attitude

What can be taken from the surveys, and can be corroborated by a number of other studies (Bredahl, 1999; Bredahl et al., 1998; Durrant et al., 1998; Frewer et al., 1997b; Gaskell and Allum, 2001), is that in Europe the public are concerned about a wide range of issues relating to GM crops. Frewer et al., (2004) identified the concerns as "*ranging from more or less concrete unintended effects such as allergies, out-crossing and development of superweeds, to worries prompted by uncertainty per se, for example unintended effects on human health and the environmental and the potential irreversibility of any negative impact*". The surveys also identified a series of moral concerns relating to GM crops "*highlighting issues like unnaturalness, 'tampering with nature', animal welfare, the power balance between producers and consumers, democracy, and disparity between the industrialised world and the third world*" (Frewer et al., 2004). Attitudes in general appear also to be related to the nature of the GM application,

applications for medical use are more acceptable then food-related applications, and food and plant applications are more acceptable then applications using animals (Dahinden, 2002; Frewer, 2003; Frewer et al., 1997a; Gaskell, 2004a; Marris, 2001; Paula and Birrer, 2006; Savadori et al., 2004; Siegrist, 2000).

There are however several studies which use alternative methods to questionnaires (Campbell and Townsend, 2003; Lahteenmaki et al., 2003; Noussair et al., 2004; Townsend and Campbell, 2004); these have shown that negativity towards GM might not be as high as initially expected from surveying attitudes. In fact a number of recent studies have shown that the public, rather then either being highly positive or negative towards GM crops, tend to be ambivalent (Costa-Font and Mossialos, 2005; Marris, 2001; Poortinga and Pidgeon, 2006), seeing the potential risks but also the benefits too. Independent of whether the public on the whole are ambivalent to the technology or negative, as Frewer *et al* (1997a) identified "*public attitudes towards the technology overall are unlikely to define acceptance; rather, the public will accept or reject applications of technology on a case-by-case basis*". This explains the relatively high acceptance of medical applications of GM technology in compared to food applications. It should be noted that Frewer's (1997) use of case-by-case is a more general definition then scientists and regulators use. Case-by-case in the sense Frewer *et al* (1997) used it is case-by-case in terms of the biotechnological application: medical applications, food crop applications, pharmaceutical crop applications; rather then case-by-case in terms of trait and crop specificity i.e. herbicide tolerant rice, corn and sugar beet (Council of the European Commission, 2001b).

The public have become a decisive factor in the future on GM agriculture in Europe (Frewer et al., 1997a; Poortinga and Pidgeon, 2005), as they will not consume foods they perceive as risky (Frewer et al., 2004) and thus have effects on the market as well as how technology is governed and regulated (Keller, 2007).

1.6.2 The role of the regulatory framework

The regulatory framework in the EU is considered by some as overly stringent and all encompassing (see section 1.5.1); yet some link the controversy over genetically modified foods to an inadequate regulatory process, "*the GM controversy can be interpreted as an expression of the inability of the policy measure set up in the 1980s*" (Frewer et al., 2004), claiming the current regulatory framework fails "*to deal with and allay the concerns of the public. Public concerns reach far beyond the risks to the environment and health addressed by the existing legislations*" (Frewer et al., 2004). In current EU GM crop regulations there is a clear separation between 'science' and public concerns or 'ethics', which despite updating of regulations (see section 1.5.1) remains firmly embedded in the "*policy world*" (Wynne, 2001). This is partly due to different perception of the inherent risks posed by the technology and the current regulatory stance that these risks need to be dealt with in a purely scientific fashion. From a natural science perspective, regulation of technology is habitually defined around scientific data, scientific understanding and expert bodies (Lonnroth, 2003). As a result public perceptions of risk have often been dismissed as irrational, misinformed and misperceptions of risk (Finucane, 2002; Gaskell et al., 2004; Mayer and Stirling, 2002) and thus excluded from the policy process by risk assessors and managers (Frewer et al., 2004). Gaskell et al. (2004) states, current regulatory frameworks "*essentially are based on the assumption that the public, like experts themselves use a risk-benefit analysis in the formation of judgements about the new technology; but that the former and not the latter assess the risks incorrectly. Both, it is assumed agree on the benefits*", this many would argue is far from the case (Flynn et al., 1993; Munnichs, 2004; Savadori et al., 2004; Sjoberg, 1998; Sjoberg, 2002). The focus and boundaries of the regulatory risk-assessment offers a poor match to the full range of public values, priorities and concerns (Grove-White et al., 1997). The failure to take into account what is driving the public's concerns resulted in the regulatory framework appearing to be unconcerned with public and environmental welfare. The concern is that "*if the public, whose voice on technological issues is more often then not measured and considered is ignored then it allows the siren voices, whether pro or anti technology, to dominate the debate with their more entrenched positions*" (Gaskell, 2004b). "*The major challenge lies in addressing the gap between the breadth, complexity and diversity*

of public concerns and the narrowness of a regulatory process that is based on circumscribed procedures of 'scientific' risk assessment" (Mayer and Stirling, 2002), and therefore, for an effective regulatory process, an understanding of the publics perception of risk is required (Finucane, 2002).

1.6.3 Factors influencing the public's perception of risk

Research indicates that the public's responses to a series of different risks will be socially constructed. As such, their perception about a hazard will influence their response to it (Frewer et al., 2004). The way in which a person perceives the risk associated with a particular hazard will have a direct impact on their attitude towards a hazard, thus "*risk perception might be regarded as a specific form of attitude towards a specific object, a potential hazard*"(Frewer, 2003).

The different perspectives that experts and lay individuals bring to the negotiation table (Finucane, 2002) underscores the importance of incorporating social and cultural dimensions in the risk debate, as the incorporation of only one will not fulfil the risk requirements of the other. This has been well documented for a variety of hazards (Flynn et al., 1993; Frewer, 2003; Sjoberg and Drozz-Sjoberg, 1994; Slovic et al., 1997). Central to the difference between public and expert perceptions of risk is the knowledge level and familiarity relating to biotechnology each holds (Siegrist and Cvetkovich, 2000). New technological hazards, like those posed by GM technology, might be especially sensitive to the 'expertise' factor because of the specialist knowledge surrounding this type of risk (Savadori et al., 2004). The expertise factor results in technical risk estimates not reflecting the social constructed risks, as the experts' perception does not psychologically represent the public's risk perception response to a particular hazard (Frewer, 2003; Siegrist and Cvetkovich, 2000; Sjoberg, 1998). It is clearly critical to identify and to attempt to bridge the void between actual or statistical risk that can be verified scientifically, and the risk that is perceived by the public (Marchant, 2001); thus a better understanding of how society evaluates risk is required; table 1.9, appendix one presents a discussion of both expert and social evaluation of risk.

Considering risk as a social construct it becomes easy to understand how technical expert-led analysis, while essential to make informed accountable risk decisions, if used as the primary component for addressing risk controversies (without reflecting on the social context of risk) is more likely to exacerbate then resolve conflict over a technology's safety (Finucane and Holup, 2005; Slovic and Gregory, 1999). Clearly the regulatory process needs to incorporate societal concerns into its evaluation of GM crops in order to reflect the deep-seated values of society (Finucane, 2002). Society's perception of the risks and the factors that influences this also needs to be taken into account. Marchant (2001) identified a number of factors which influence the publics perception of risks; these will be discussed below.

1.6.4 Integral qualities of the technology which effect public perception

Slovic *et al* (2002) emphasised the need to consider the role of 'affective process' in risk perceptions, the so called "*affect heuristic*". This is when the traditional assumption that beliefs about risks are held prior to evaluations of risk are reversed, so that preferences (evaluations of risks) shape beliefs. The affect heuristic can explain why two risks which have equally uncertain outcomes can be perceived differently if the outcomes of one are more attractive then the outcomes of others (Gaskell, 2004a). When applying the affect heuristic to GM it might go someway to explaining why some applications of the technology have been accepted to a greater extent then others, for example medical applications in relation to agricultural ones.

Slovic's earlier work (Slovic, 1987; Slovic, 1992) identified a number of dimensions (factors) of risk judgement, which explained risk perception to a variety of different potential hazards (Siegrist, 2000). They discovered that the degree to which a hazard is dreaded was closely linked to the level of riskiness attributed to that hazard and that dread risk consistently emerged as the most important factor in explaining perceived risk (Townsend, 2006). Even prior to its

applications in medicine and agriculture Slovic identified that DNA technology, (biotechnology), along with nuclear power, was high on the factor 'dread risk' and moderately high on the factor 'unknown risk'(Slovic et al., 1985). This suggested, in essence, there are two main qualitative dimensions that seem to drive societal risk perceptions of GMO: dread risks (not dreaded vs. dreadful) and unknown risk (known vs. unknown) (Finucane, 2002). Indeed, in people's minds DNA technologies were perceived to be very similar to hazards such as nuclear energy, radioactive waste, electromagnetic fields and other technologies which use rays or chemical substances (e.g. food irradiation and food colouring) (Savadori et al., 2004). GM technology, in particular GM crops, have many features of dread risk and unknown risk, (Finucane, 2002) these are presented in table 1.10. Thus Slovics' (1985) study suggested that even before GM became the focus of controversy, it was a potential source of concern to the public (Gaskell, 2004a) and more recent work has supported that this is the case (Beck, 1992; Hoban, 1997; Hoban, 1999; Sparks and Shepherd, 1994; Torgersen et al., 2001). In particular Sparks and Shepard, (1994), who identified that compared with other food hazards, GM food was considered a moderately severe risk and a very unknown risk. Indeed, Townsend and Campbell (2004) recognized that dread and risk to future generations predicted about half of the variance in the publics future willingness to purchase GM food.

As already discussed, scientists measure risk as primarily a function of probability, (appendix one, table 1.9); however, public perceptions of risk incorporate many other non-technical factors (Slovic, 1987). Non-technical factors such as the concept of dread and unknown risk need to be addressed, if public perception is to be understood and altered. As Loewenstein *et al* (1990) emphasized in their '*risk-as-feeling hypothesis*', emotions like fear and dread have a pivotal role in risky decision making.

Table 1.10: Outlining the features of dread and unknown risk present in GM technology taken from (Finucane, 2002).

Dread Risk	Food growers are the ones who decide whether to use GM seeds or other products so consumers do not necessarily have a choice (involuntary exposure). Many individuals are exposed to GM foods (signalling global catastrophic potential). The risks and benefits are not fairly distributed (currently the benefits are greatest for the farmers and GM food manufacturers rather then the consumers). Children are heavy consumers of some products making parents even more sensitive to the potential harm.
Unknown Risk	To some individuals GM technology seems very risky because they are based on relatively new science (so scientists do not have enough knowledge to estimate the risks accurately). The inadvertent introduction of harmful changes in DNA structure is not immediately obvious (the effects are delayed). Consumers do not necessarily know when they are exposed, because they are not well informed about which products contain GM ingredient and GM is not obvious to the causal observer.

1.6.5 Public perception driven by a predominantly negative press campaign by Non-Governmental Organisations (NGO) and the Media

1.6.5.1 The role of the media

The media play a crucial role in the distribution of information, as Kasperson et al., (1988) stated, information about risk and risk events reaches individuals through two primary communication networks: the news media and informal personal networks. Three Mile Island is a great example of how even tiny incidents, if deemed important, will be covered in the news media, and that this attention could and does completely change the public's perception of the technology (Siegrist, 2000). GM has been associated with a great deal of media attention, both in the UK and Europe, which is largely negative and often emotional in tenor (Bonny, 2004; Gaskell, 2000; Scott, 2000; Townsend, 2006). A great example is the Daily Mail's coverage of Bayer's GM maize once the government announced it planned to approve it, "*so we're going to be forced fed GM... ...[when] 90% of Britons oppose the growing of so-called 'frankencrops' and the sale of food derived from them*" (Gaskell, 2004c). When media reporting of GM foods was at its height in the UK, in 1999, it was characterised according

to (Frewer, 2003), by several factors: "*a large volume of information which may serve as a risk amplifier (which increases public perceptions of risk), independent of the accuracy and actual content of the information; disagreement between various actors in the risk debate; dramatisation of risk information (through presentation of risk 'scenarios' and examples); and the symbolic connotations of terms or concepts used on messages*".

Some see the public as the victim of misleading information from newspapers that are seeking to increase their circulation numbers (Burke, 2004); regulatory institutions and the scientific community have often associated the media with the promotion of distrust in science regulations, that the "hysteria" in the press has resulted in the public's negativity toward GM. (Frewer, 2003). Some go as far as to blame the media for the faster ignition and wider spread of modern controversies (Hines, 2001). Indeed sometimes a particular risk event does gain sufficient media coverage to either trigger public fears or to mobilise collective fears, resulting in an increased perceived risk; however it is unclear whether increased discussion of the risks of GM technology in the media does have a long-term impact on people's risk perceptions. Studies by Frewer (2003) seems to suggest that negative media reporting had "*neither a great or enduring*" effect on perceived risk but a permanent effect on perceived benefits; that the associated "*public negativity about emerging technologies with so called 'press hysteria' is probably over-stating the case*".

1.6.5.2 The role of NGOs

A number of organizations have take up 'the issue' of several applications of biotechnology and have joined opposition to GMOs (particularly agricultural applications) (Bonny, 2004). These include: environmental organisations, such as Friends of the Earth and Greenpeace; green political parties, like the Wessex Law Association; organic food associations, such as the UK's Soil Association and France's Confederation Paysanne; as well as anti-globalisation groups, like the Association for the Taxation of Financial Transactions for the Aid of Citizens. The role of NGOs is often discussed in relation to the role of the media: both are

charged with the production of the controversy surrounding GM due to reports and protests which are "*frequently peppered with hostile, negative and emotionally charged messages*" (Scott, 2000). NGO actions, protests, civil disobedience and violent acts (e.g. destruction of GM field trials) have also been widely reported by the media (Durrant, 2005), giving it a certain amount of credibility.

NGOs tend to provide a clear message on GM which reinforces many people's concerns, unlike the often contradictory messages received from scientific experts that are often highly laden with caveats (Bonny, 2004). The arguments put forward by NGO opponents often call for caution and wisdom in the use of the technology, the need for care and concern about environmental safety and public health for the good of the future planet, as well as public inclusion in decision making. These arguments call upon *a priori* values which naturally generate support (Bonny, 2004), and shows NGOs in a good light, as having a responsible attitude, thus conferring legitimacy upon them. The actions of NGOs have not just influenced the public, indeed the rapid growth in the transnational policy networks of oppositional NGOs is believed to be one of the main drivers behind regulatory disputes between the Competent Authorities of Member States and the European Parliament (Levidow et al., 2000).

Again, in the views of some in the science and regulatory community, the public have been seen to be victims of misleading information generated by NGOs and facilitated by the media (Burke, 2004; Renn et al., 1992). However the actual role NGOs and other campaigning groups have had is somewhat disputed. While some feel they are the drivers of public unease about GM crops through a one-way dialogue (Burke, 2004; Dale, 1999), others feel that NGOs are followers rather then leaders of public opinion (Mayer and Stirling, 2002) and "*that the public, rather then accepting their arguments carte blanch appreciates the role NGOs have as critical dissenting voices*". This has been supported by research conducted by Marris *et al* (2001) who found that environmental NGOs were "*appreciated for their capacity and willingness to ask difficult questions and raise issues which*

would not have been raised otherwise", but they also were "*perceived as biased just like other actors and recognised to have their own vested interests such as raising funds and membership*" indicating that the public are not just blindly accepting of NGO information. The research by Marris *et al* (2001) supports the notion that "*the public attitude towards NGOs is active and knowing rather then passive and credulous*" (Mayer and Stirling, 2002). That rather then driving public attitude, NGOs tend to have shared values that are representative of the public's concern.

The role NGOs should play in the GM debate is a controversial one (Burke, 2004; Grove-White et al., 1997; Mayer and Stirling, 2002), but perhaps there is a valid argument for their inclusion within the policy making framework. The Netherlands makes an interesting case for this. In the Netherlands, political culture promotes a more participatory than controversial role for NGOs in policy making (Dahinden, 2002). Some believe, as a result, that the Dutch debate on biotechnology has contrasted strongly with the debates in the UK, Germany and Belgium. In the Netherlands there is general consensus in favour of biotechnology and a relatively high trust in public institutions. The Dutch opinion-leading press have also presented biotechnology neutrally. While there are a number of other factors which could go some way in explaining the difference between public attitude in the Netherlands and other EU Member States, it makes a convincing argument for NGO inclusion in the decision making process.

1.6.6 Public attitude as a result of their general level of knowledge, information and understanding

1.6.6.1 Understanding and knowledge

The findings of a PABE (Public Perceptions of Agricultural Biotechnology in Europe) survey concluded that understanding the nature of genetic modification was limited (Marris, 2001), for example the majority of Swiss people were unable to correctly answer a basic true/false question about gene technology, "*it is impossible to transfer animal genes into a plant*" (Siegrist, 2000). A number of

studies have also drawn the conclusion that the public are lacking in knowledge and understanding of biotechnology (Allum et al., 2002; Council of the European Commission, 2000; Eden, 1998; Sjoberg, 2001)and therefore are ignorant about both its risks and benefits. While the public might lack knowledge about biotechnology and science in general; Marris (2001) argues that they are not ignorant, as those surveyed in the PABE poll identified their lack of knowledge and therefore were conscious of their technical limitations. The ERSC report (1999) supports this, stating that "*there is much evidence to suggest the assumption of public ignorance is wrong on a number of fronts*".

There are arguments that if you improve the public's understanding of biotechnology this could be the way forward as a more knowledgeable public is likely to be a more supportive one (Gaskell, 2004b). While Gaskell himself does not concur with this, "*I do not believe that the controversies over GM foods were driven by public ignorance, rather the real issue is not so much about the science, but rather about the type of society that new developments in science and technology make possible*"(Gaskell, 2004c). Others would argue increasing societal understanding, and therefore knowledge, does have a role in shaping societal attitudes and perceptions of GM crops, especially in what is becoming a knowledge-based society (Braun, 2002). Wolt and Peterson (2000) gave a number of reasons for this "*personal and societal knowledge as a factor shaping perceptions and public attitudes towards agricultural biotechnology has been discounted by some, in part, because of the failure of scientific arguments to sway attitudes and public policy making,* "; however they blame the framing and communication of scientific issues to the public for the limited influence increased knowledge has on swaying attitudes. "*As at the most fundamental of levels, all risk is perceived and as such knowledge values and ideology will determine how risk is perceived*" (Wolt and Peterson, 2000). In cases where knowledge is lacking then risk perception will be formed either from preconceived values and ideologies, thus skewing risk perception towards the more emotive attributes of risk: those which cause fear, anger, defensiveness or frustration (Foundation of American Communication, 1995). Alternatively it will require the public relying on information provide by experts (Siegrist and Cvetkovich, 2000).

To address the clear knowledge and understanding deficiency, it has been argued that the public should be better educated in the area of science so that consumers can form coherent opinions and make rational choices (Frewer et al., 1996). The European Commission clearly sees improving knowledge as important, it aims to improve knowledge about biotechnology through its EIBE (European Initiative for Biotechnology Education) program (European Initialtive of Biotechnology Education, 2000) which provides educational materials to teachers. The long-term hope for programs like this is that they will enable citizens to make sounder decisions on the way society should move in the future (Braun, 2002). This is, however, a difficult task as people may not be interested, or possess the basic scientific knowledge (Miller, 1998).

1.6.6.2 Educating through information

The knowledge deficit model was central in the drive to 'inform' the public about biotechnology. The model came from a number of studies (Allum et al., 2002; Evans and Durant, 1995) which identified a knowledge deficit between science and public understanding. It was therefore assumed that if society better understood the science and technology underlying GM, they were more likely to accept GM research, development and technology (Durrant, 2006). As a result a number of multinationals and governments pursued public information campaigns as an antidote to what they characterised as misinformation by GM food opponents (Durrant, 2006). Indeed studies have shown that there is a societal desire for more information about GM (Poortinga and Pidgeon, 2004; Rosati and Saba, 2000) and that currently there is a heavy reliance on the media as the primary source of public information (Kasperson et al., 1988). There have been a number of studies looking at the effect increased information about biotechnology has on public opinion. Frewer et al., (1998) found that when presented with persuasive messages about GM (from different information sources both pro- and anti-GM) the attitude of British consumers towards GM became increasingly polarised, i.e. those with already negative attitudes became more negative and those with positive attitudes became more positive. There are however a lot of

people who fall somewhere in the middle in terms of their initial attitudes towards GM in that they can identify the risk but also see the potential benefits too; this subset have been labelled ambivalent (Pidgeon et al., 2005; Poortinga and Pidgeon, 2006) as when attitudes are conflicted prior research reveals that respondents typically engage in a process of 'averaging' (Zaller, 1992). With ambivalence, often additional information makes the simultaneous factors (the core values held about the technology i.e. perceived risks and benefits) more salient, which in turn makes it more difficult for an attitude towards biotechnology to be resolved (Alvarez and Brehm, 1995). The less certainty and more ambivalence one finds among respondents, the more questionable becomes the assumption that information campaigns will aid and clarify the public's attitude towards biotechnology (Durrant, 2006) thus it seems likely that greater amounts of scientific and biotechnological information would be in some cases self-defeating.

Clearly, in a society which considers itself to be knowledge-based, as both the UK and EU does, the levels of knowledge and understanding the public have both in terms of biotechnology, and science more generally, does need to be addressed. Providing the public with information and improving their scientific education has played a central role in this. However the assumption that increasing the public's knowledge and understanding about biotechnology will automatically make them in favour of it is naïve. Public attitudes have been shown to be remarkably resistant to change (Frewer, 2003), independent of the information or sources of information available to them. This further supports the arguments that experts and the lay public evaluate risks differently, as expert evaluation relies on knowledge and understanding of the risks gained from the best information available; whereas availability of information does not seem to have much effect on the public's attitudes, if anything it just further entrenches the attitudes they already have.

1.6.7 Public perception driven by their trust: in science, regulations and those involved in the regulatory process

1.6.7.1 Trust as a substitute for knowledge

One way for the public to cope with a lack of knowledge is to rely on social trust to reduce the complexity of risk decisions (Earle and Cvetkovich, 1995; Siegrist and Cvetkovich, 2000; Wolt and Peterson, 2000), in essence trusting someone with greater knowledge to make these decisions on your behalf. As the public have relatively little knowledge about biotechnology, and indeed science, trust in those involved with the science and regulation of biotechnology is critical for its acceptance (O'Neil, 2002). Freudenburg's (1993) study looking at the public's attitudes towards nuclear waste disposal illustrates this. Those who placed trust in current scientific and technical abilities to build safe nuclear waste disposal sites were less concerned about a hypothetical nuclear waste repository in their country then people with no trust in the relevant institutions. A number of other studies have also drawn similar conclusions (Cvetkovich, 1999; Flynn et al., 1994; Flynn et al., 1992).

Indeed, credibility and trust in information sources plays a major role in how society reacts to novel products (Frewer et al., 1995): trust helps us reduce uncertainty to an acceptable level and simplify decisions involving large amounts of information (Savadori et al., 2004). High credibility of information sources, like trust in risk management, was found to be inversely correlated to risk perception (Jungermann et al., 1996). Unsurprisingly, information provided by research institutes and environmental groups was trusted the most, followed by political, organisations while information provided by industry was trusted the least (Savadori et al., 2004).

1.6.7.2 The need for trust in order to gain acceptance of biotechnology

The lack of faith in the information given by institutions involved in gene technology was a significant predictor of opposition towards genetic engineering (Siegrist, 2000). Siegrist (2000) suggests this is because trust (in companies and

scientists involved with biotechnology) has a strong effect on how the benefits and risks of biotechnology are perceived and that acceptance of a technology is determined by the perceived benefits (see section 1.6.8). Therefore, trust has an indirect effect on the acceptance of the technology (Siegrist, 1999). Further more, the relationship between risk perception and trust strengthened as knowledge of the activity decreased (Siegrist and Cvetkovich, 2000). A number of other studies have also recognised the importance of social trust in the public's judgement formation about risk and benefits and the acceptability of technologies (Cvetkovich, 1999; Earle and Cvetkovich, 1995; Finucane, 2002; Finucane and Holup, 2005; Savadori et al., 2004; Siegrist, 1999; Siegrist, 2000; Slovic, 1993; Slovic et al., 1997).

1.6.7.3 The loss of trust in science

There have been several crises of confidence regarding science and its application (Davies and Wolf-Phillips, 2006), which have rocked public confidence in scientific advances. Surveys like the Eurobarometer have shown that the public's trust has shifted away from scientists, universities and the government, towards medical professionals and environmental groups (Marchant, 2001). Indeed a House of Lords report in 2000 entitled 'Science and Society' produced by the Select Committee on Science and Technology (House of Lords Select Committee on Science and Technology, 2000) emphatically acknowledged a widespread crisis of public mistrust of science used. This has been echoed at a European level with the publishing of the 2001 White Paper on Governance which contained a chapter on science and citizens within which public trust was a central issue (Wynne, 2006).

Several studies have shown that trust is easier to lose then it is to gain (Kasperson et al., 1992; Poortinga and Pidgeon, 2005; Savadori et al., 2004; Siegrist, 2000; Siegrist and Cvetkovich, 2000; Slovic, 1993). Thus an event with negative consequences could have disastrous impacts on trust and will result in decreased acceptance in biotechnology (Siegrist, 2000). Three Mile Island again is a clear example of the enormous impact a relatively 'harmless' incident can have;

negative events (that will often lose trust) are frequently highlighted by the media and anti-campaigners while positive ones are taken for granted (Siegrist, 2000). Interestingly, people with different attitudes draw different conclusions from non-catastrophic events. Work by Plous (1991) suggests that supporters of a technology interpret near misses as evidence that safeguards had worked, whereas the same events negatively influenced opponents' trust in the safeguards to prevent future accidents. A number of highly publicised incidents have rocked the public's trust in science and the way in which science is regulated (Marris, 2001; Mayer and Stirling, 2002; Pidgeon et al., 2005; Savadori et al., 2004); BSE, thalidomide, nuclear power, dioxin contamination of dairy products, and DDT have all provided the public with examples of how failure to adequately regulate scientific advance can have negative impacts on both society and the environment (Braun, 2002; Davies and Wolf-Phillips, 2006; Finucane and Holup, 2005; Lonnroth, 2003; Millstone and van Zwanenberg, 2000). However Wynne (2006) questions the extent of influence these have had on public mistrust.

The crisis in trust stems from fundamental issues with science rather then singular events (Davies and Wolf-Phillips, 2006; Mayer and Stirling, 2002; Wynne, 2006); "*if the science that is funded, or the attitudes underpinning it, are at odds with broader societal values trouble may emerge*" (Mayer, 2003). Davies and Wolf-Phillips (2006) blame part of the underlying problems with trust on the lack of distinction between, "*science, the exploration of the external world for its own sake and its application in technologies that are implemented to solve problems*". That science is often done for the sake of scientists rather then the wider public and, as such, the concerns of the public and implications the science may have on the public are not taken into account. Another concern is that, in recent decades, there has been a blurring of boundaries between science and its applications through the actions of commercial companies and government. As a result, the public are beginning to question the drivers of science. The so called scientific 'gatekeepers to knowledge' are also changing according to Graham (2002). Whereas they once were the editors of peer reviewed journals, they now could be argued to be committees and referees which grant funding for proposals; as a scientist is not only now judged on the work he has done (work published) but the

future work (and money) he is going to bring in. Nowhere is this more apparent then in academic institutions. The concern about the new gatekeepers to knowledge is that many grant awarding bodies have industrial representatives with commercial interest, "*therefore, the potential for conflicts of interest to arise within the grant awarding process itself is increasing*" (Davies and Wolf-Phillips, 2006). This is a concern echoed by Mayer (2003) as "*the financial controls on science are, perhaps, the most important determinants of the scientific knowledge we generate, funding agencies decide what is worthy of support, build fashions in science and gather intellectual and economic support for certain scientific approaches*". Even at the university level, there is a concern that commercial interests are prejudicing scientific knowledge and this is undermining the whole peer review process (Washburn, 2005). These conflicts of interest between science and its drivers centre around scientific ownership, Wilsdon and Willis (2004) recognize a need for these "*deeper questions about values, visions and vested interests that motivate scientific endeavour*" to be asked, if public trust in the pronouncements about science is going to be regained and the wedge between science and society is to be lessened.

Finally, proponents and scientific experts have come under criticism for overextending the potential benefits or usefulness of the technology. Van Dommelen (1999) criticises scientists who fail to resist the temptation of making claims to the public about the technology for which no scientific proof can be offered. Claims such as GM being a necessary prerequisite for feeding the world's population in the future, or as a cure for, blindness in the third world or even bird flu, are perfect examples of over claiming GM's potential resulting in unsubstantiated claims which can be easily disputed. Thus there needs to be a scientific refrain from answering so-called trans-scientific questions, "*that can only be stated in the language of science, not answered by it*" (Munnichs, 2004). Again science needs to sit within the context of the wider societal issues that technology is positioned within. It needs to address these concerns, but also to know its place in terms of the answers it alone can provide. O'Neil's book, "*Autonomy and Trust in Bioethics*" (O'Neil, 2002) gives considerable insight into the issues surrounding societal trust in biotechnology.

1.6.7.4 Trust in the regulatory process

Trust is particularly important in the public sector, as these institutions often have the specific duty to protect the public from various risks (Poortinga and Pidgeon, 2005); therefore trust in public institutions to effectively regulate and control technological risks is generally seen as an important factor in the acceptability of these risks. Considering the importance of public trust, it might concern proponents of GM that less than half (45%) of the respondents in the 2000 Eurobarometer survey felt that the governments are regulating biotechnology well enough. Trust in institutions is closely related to the perception and acceptability of various risks (Flynn et al., 1992; Freudenburg, 1993; Siegrist, 1999; Siegrist et al., 2000). Earle and Cvetkovich (1995) argue that shared values constitute the foundations of trust, so if an institution's behaviour is judged to reflect a person's values in relation to risk, the institution will be seen to be trustworthy. As people's knowledge of biotechnology is rather limited, the values they hold in relation to biotechnology would also be limited and as such general. Thus general beliefs and values, such as world views, would be expected to have an important influence on trust. This has, indeed, been shown to be the case in a number of studies (Buss and Craik, 1983; Earle and Cvetkovich, 1997; Peters and Slovic, 1996; Siegrist, 1999) where world views have a significant influence on trust in institutions responsible for or regulating biotechnology and the assessment of associated risks and benefits related to the technology.

Some like Kasperson *et al* (1999) identified the sensitivity of trust in institutions to specific events, such as the BSE crisis. Others however, relate trust, or rather mistrust in institutions to fundamental institutional practices, "*it remains true that institutional science in many domains, from new technologies, to public health and environment policy across the board does indeed suffer from association in public experience with problematic and sometimes downright provocative institutional conditions, practices, assumption, purposes and inconsistencies; and these are conducted in the name of science, normally with silent acquiescence or positive support from scientific institutions*" (Wynne, 2006). Central to concern put forward by Wynne (2006) is that there appeared to be a double standard between how science is judged when it is critical science questioning a GM crop, as opposed to when science is used as part of the industrial application seeking

regulatory approval. The latter, it is feared, is examined with less vigour (Mayer, 2003). Indeed, opponents felt this was proved beyond doubt when Friends of the Earth gained an injunction which enabled them to get scientists to independently review an application for regulatory approval which had been accepted by expert committees in the UK and EU (Alesbury, 2000).The application was for Chardon LL, a variety of GM maize. The independent review by Friends of the Earth found that a food safety test involving chickens was flawed because it didn't have the statistical power required to detect difference between the chickens fed on GM maize and those fed on conventional varieties (DEFRA, 2003). This, they felt, proved that scientific information used for regulatory approval was not reviewed to the level required, and the fact that the independent review for Friends of the Earth was not considered enough proof to remove regulatory acceptance (Bayer, the manufacturer, actually removed Chardon LL from the market rather then the regulators) was further proof that critical science was judged more rigorously.

The concerns about trust are not only about industrial agendas running the science and regulatory process, but also the government's agendas. It seems to be a common governmental belief in the EU and UK that independent of the wider uncertainties, GM crops are at least beneficial for agriculture (Levidow, 1994). The Commission of the European Community policy documents (Council of the European Commission, 1991b) show the EU supporting the research and development of biotechnology and are dominated by considerations of industrial competitiveness and economic growth. In the UK, this was also seen with the replacement of the Agriculture and Food Research Council with the Biotechnology and Biological Science Research Council, which reflects the change in emphasis of agricultural research (Mayer, 2003). With governments at both national and international levels seen to be pushing biotechnology, it is easy to understand why some are questioning the independence of the regulatory process.

1.6.7.5 Trust in experts

The importance of trust between the public and experts has often been noted (Finucane, 2002; Flynn et al., 1993; Marchant, 2001; Rosati and Saba, 2000; Salter and Jones, 2002; Savadori et al., 2004; Siegrist, 2000) and is termed social trust i.e. "*the willingness to rely on those who have the responsibility for making decisions and taking actions related to the management of technology, the environment, medicine, or other realms of public health and safety*" (Frewer et al., 2004; Siegrist et al., 2000). In Europe, unlike America, public officials and technical experts are viewed as untrustworthy (Wolt and Peterson, 2000). In a survey of the public in 17 European countries, the respondents showed a low level of trust in national public bodies "*to tell the truth about GM crops grown in fields*" (Bonny, 2004; Gaskell et al., 1999). High levels of public mistrust in regulatory experts combined with limited knowledge results in heightened risk perception and lower public acceptance of biotechnology (Gaskell et al., 1999). There are a number of studies which have shown the importance of social trust in relation to expert judgement of new technologies (Flynn et al., 1992; Jungermann et al., 1996; Siegrist et al., 2000).

Differences in expert opinion, go part way in explaining the underlying mistrust, experts are not a homogeneous group as they often differ in their assessment of a technology (Munnichs, 2004; Sjoberg, 1998). The public, due to their overall lack of knowledge and understanding, find it difficult to evaluate the accuracy or reliability of information about risks and benefits associated with modern technologies given by different sources (Siegrist and Cvetkovich, 2000). "*NGOs have increasingly made use of their counter-expertise to cause doubts on the validity of "official" expertise*" (Munnichs, 2004). The public, thus, become more familiar with the notion that experts frequently disagree: this has implications when expert evaluations are required for dealing with new technologies. When it comes to the public needing to choose between expert opinions, it has been suggested that people have trust in experts who share the same values as they do about a technology (Cvetkovich, 1999; Earle and Cvetkovich, 1995; Earle and Cvetkovich, 1997; Munnichs, 2004; Siegrist and Cvetkovich, 2000). As the public often share more of the same wider reaching values with NGOs and their advisors

(Mayer and Stirling, 2002), than they do with the relatively narrow regulatory process and associated experts, it is understandable that the public are often sceptical of expert regulation of biotechnology.

Another factor which is vital to ensure the public's trust in experts is their scientific independence; scientist and regulators therefore need to ensure their independence and objectivity (Munnichs, 2004). Research by Pollara and Earnscliffe (2001) recognizing that those seen as stakeholders in GM technology, including scientists who are believed to be influenced by corporate research funding, are not seen as providers of accurate information (Marchant, 2001). The question arises as to the conditions in which the public would deem experts or expert bodies trustworthy (Munnichs, 2004); certainly scientific independence would be one such condition.

1.6.7.6 Gaining trust

A number of attempts have been made to reclaim trust by several organisations (Fischhoff, 1995; Pidgeon et al., 2005). These attempts have centred on communication efforts aimed directly at increasing trust, which might not be universally effective and could even be counterproductive (Fischhoff, 1995). As Poortinga and Pidgeon (2005) identified, "*the reason communications directed at increasing trust are ineffective is that trust in regulations is strongly dependent on someone's general attitude. It is more likely that trust will be increased only through understanding and addressing the underlying concerns about that particular issue*". This stressed the importance, then, of two-way communication of risk issues; rather then the one-way deluge of information about risk which is currently favoured (Wynne, 2006). One-way communication may be interpreted as not taking public concerns seriously, and is therefore more likely to destroy than create trust. This sentiment is echoed by a number of other authors (Braun, 2002; Costa-Font and Mossialos, 2005; Frewer, 2003; Marchant, 2001; Pidgeon et al., 2005); and eloquently put by Bier (2001) "*one must start with listening to the concerns of the public before giving them new information*".

Trust in a technology can be increased if the technology is framed to reflect the public's salient values. The reframing of some applications of food biotechnology so that they appear similar to medical applications have been seen to be beneficial (Siegrist, 2000). Probably most important, is the clear incorporation of the public views into the regulatory and decision making process, in an open and transparent fashion (Davies and Wolf-Phillips, 2006; Frewer, 2003; Frewer et al., 2004; Marchant, 2001). "*The principle challenge lies in addressing the gap between the breadth, complexity and diversity of public concerns and the narrowness of the regulatory process that is based on the circumscribed procedures of 'scientific' risk assessment*" Mayer and Stirling (2004). Scientists should be expected to have an understanding of the philosophy which puts the science they are undertaking into context (Davies and Wolf-Phillips, 2006). Recent suggestions to infuse scientific culture and practice with social possibilities (Wilsdon, 2005) is one way of doing this; Johnson et al., (2007) cited the requirement for this in their paper considering the need to include risk assessment within the wider context of risk analysis; which would enable the scientific quantification of risk to be seen within the context of societal drivers (the management goals and assessment endpoints) of the risks assessment process.

Opening the dialogue between scientists and society is another way of improving trust. The Royal Society (2004) in their report "Science and Society" suggest ways of doing this, however some feel that the only way to heal the rift between biotechnology and society, in terms of trust in the regulatory process, is to move the dialogue downstream (Davies and Wolf-Phillips, 2006). This proposal is made on the basis that science and scientists need to understand the philosophical and social context within which scientific endeavour takes place. Barling *et al* (1999) describe a process for integrating risk analysis with social impact assessment as a means of linking trust and knowledge in risk judgements concerning food biotechnology. While stressing the importance of scientific risk assessment underlying the process, Barling *et al* (1999) also includes social analysis in the form of expert panels, citizen juries and depth surveys as a way of soliciting and

acknowledging public input, other authors suggest similar measures to ensure public inclusion is felt (Gaskell, 2004c; Pidgeon et al., 2005; Wolt and Peterson, 2000). Some however question the validity of citizen inclusion (Munnichs, 2004) suggesting that "*experts who share the same worries as (parts of) society about possible hazards could be expected to voice their worries on the same level of scientific dispute*".

Independent of the means of doing it, one thing is apparently clear, there needs to be the obvious, and open, inclusion of the wider societal concerns in the regulatory process for the process to start to regain society's trust. While it only includes the scientific concerns of experts involved in the process, then there will always be criticisms levelled at the scope of the process, the impartiality of experts and the validity of the underlying science.

1.6.8 Public perception and the role of the benefits of GM crops

"*One of the defining elements of an innovation, for example a new technological development, is that it offers benefits over and above what is currently available. An innovation without such additional benefits is almost an oxymoran*" (Gaskell et al., 2004). Improvement over what is currently available through current conventional practices is a real sticking point for agricultural biotechnology applications.

Proponents of GM technology claim that it offers a range of benefits to a variety of beneficiaries (Gaskell, 2004a), however very often GM crops are not seen, by the public, as having direct benefits for the consumers. In fact "*the benefits expected in return appear to be only slight or even nonexistent, especially from the types of transgenic plants that have been developed so far*" (Bonny, 2004). This absence of perceived benefits for the consumer is considered the 'Achilles heel' of GM crops (Gaskell, 2004a). The importance of benefits can be seen by the contrast in the public's acceptance of medical (which the public judge to have societal benefits) and agricultural applications of GM technology (which is view as not to yielding societal benefits) (Fischhoff et al., 1984; Frewer, 2003;

Marchant, 2001). As Millstone and van Zwanenberg (2000) argue "*there are few reasons to doubt that they would welcome a GM cure or even treatment for aids, cancer, Creutzfeldt-Jakob disease or arthritis, just so long as they perceived the innovations to provide benefits to themselves that outweighed the personal risks*".

While the actual risk from a GM products are considered to be immutable (Marchant, 2001), if the benefits appear to outweigh the perceived risks then the level of outrage should be reduced. Indeed Gaskell et al., (2004b) found that in some circumstances "*there was a possibility that benefit perception might 'trump' risk perception*". It may therefore be assumed that risk perception and benefit perception in some cases are inversely functionally related (Frewer et al., 1998; Savadori et al., 2004; Siegrist and Cvetkovich, 2000), however whether this is a causal relationship is disputed (Frewer, 2003; Siegrist, 2000). This implies that the acceptability of a technology that is perceived to be high risk could be increased, if the benefits are understood (Braun, 2002; Savadori et al., 2004; Siegrist et al., 2000). Indeed, the Mellman study in 2006 showed an increase in acceptance of the technology if the benefits were obvious. It should be noted that, although the lack of perceived benefits by society is likely to be a contributory factor to consumer rejection, as Frewer (2003) stated "*it would be an oversimplification to assume that the public will automatically be positive towards products that do have tangible consumer benefits*". One of the reasons for this is that even if the benefits of the technology are acknowledged, there is also concern about the spread of these benefits (Tait, 2004). "*There is the perception that while genetic engineering might boost profits for the handful of firms directly involved, it is of practically no benefit to the rest of society which never-the-less has to face what are perceived as substantial risks*" (Bonny, 2004). The uneven spread of benefits is particularly apparent with the crops that are currently commercialised, the majority of which are aimed at decreasing inputs, like chemical pesticides, which benefit the farmer but do not provide obvious benefits for the consumer (Keller, 2007; Laget and Cantley, 2001; Paula and Birrer, 2006; Wu, 2004). A number of scientists remain optimistic about future GM crops that might provide more obvious benefits for society (Braun, 2002; Burke, 2004). There are numerous examples of future GM crops being developed where the potential benefits are aimed at the consumer

rather then the producer: for Developing Nations, rice with increased iron or vitamin A content and nuts without allergens or healthy oils for Developed Nations (Braun, 2002; Frewer et al., 1997a) (see section 1.3.4). However public opinion towards these 'second generation' crops with perceived societal benefits was more hostile then to 'first generation' input trait crops (Frewer et al., 2004).

One of the reasons the public acceptance does not seem to be as linked to benefits as initially presumed, is that discussion of benefits and how these will improve societal acceptance of GM crops, is to an extent, flawed. It is flawed because it is often held at an expert level, and as already discussed with the risks expert perception differs from societal perception. Thus there is likely to be individual difference in what constitutes a societal benefit between a lay-individual and an expert. To an extent, this has already been shown: expert consideration of benefits (within EU policy, expert consultations and technological reviews (Council of the European Commission, 2000; OECD, 1994; Scholderer et al., 1998; Scholderer et al., 1999; Uzogara, 2000b)) suggest that benefits relating to health and sustainability claims have the greatest potential to improve consumer acceptance. However, a recent study of public attitudes (Frewer, 2003) demonstrated that neither type of benefit is persuasive for the acceptability of specific GM products when consumers are presented with concrete product examples of the GM food exhibiting either trait. Frewer (2003) explains this "*almost certainly because consumers are not homogenous concerning what they regard as a personal benefit and perceptions of what actually constitutes a benefit are likely to vary between individuals*".

Providing society with information about the benefits, through communication detailing such benefits, is a key step in reducing outrage (Savadori et al., 2004), however this needs to be done sensitively, from parties held by the public to be independent and trustworthy, otherwise the benefits might not be accepted. Wider society, as well as scientists, needs to be able to weigh up the risks and benefits a GM crop possesses before they can make an informed judgement about adoption of that crop (Wu, 2004).

1.6.9 Summary

"*Social acceptance of biotechnology is to a great extent dependant on the presence of: a perceived benefit to the consumers under acceptable risk, adherence to key moral values regarding human and non-human life, and trust in the governance of the technology*" (Paula and Birrer, 2006).

There is an urge to dismiss societal concern as ignorant or Luddite. This must be resisted, as, although public opinion is often based on emotive perceptions rather then scientific fact, these concerns are equally legitimate. By not addressing these concerns, the regulatory process is adding to the controversy over GM crops rather then alleviating it (Frewer et al., 2004). Public acceptance of GM technology and the regulatory process is crucial if agricultural applications of biotechnology are to ever be commercially grown and market in Europe. The European Commission identified that "*without public acceptance and support, the development and use of life science and biotechnology in European will be contentious, benefits will be delayed and their competitiveness will be likely to suffer*" (Salter and Jones, 2002). The public acceptance issue is probably a bigger concern for science in general. Trust in science, scientists and regulators have diminished for a variety of reasons. Not least due in part to a series of well publicised scientific crises that have rocked public confidence in scientists and the government to regulate scientific advancement. GMOs, especially agricultural applications, are perhaps seen as the next BSE or nuclear power, the next human health or environmental crisis brought about by adopting new scientific technologies.

Society needs to be brought on board both in terms of the science but also in terms of the regulatory procedure governing the science. This means scientific regulations can no longer be purely science based, as their judgements are statements not only about the safety but also about the public acceptability of a new technology (Salter and Jones, 2002). Societal concerns and levels of acceptability needs to be incorporated into the regulatory framework in order for

society to feel that its issues are being addressed, and this needs to be made explicit (Frewer, 2003). When it comes to assessing risks, while scientists generate the necessary information about the risk, society needs to be one of the main drivers behind what is acceptable and what is not. Too often it is felt that acceptability thresholds set by scientists are being forced upon society, who perceive the risks and benefits in a totally different way and as such might not accept them. As Marchant (2001) identified "*science needs to acknowledge the social contexts affecting risk perception and that public opinion must be taken into consideration*".

Lonnroth (2003) proposes better risk leadership which proceeds slowly with the main objective to build trust. In doing this, he recognised that we must "*see the regulatory process as a broad social process rather then a narrow expert issue... ...declare openly where there is a lack of scientific knowledge but a decision nevertheless have to be taken... ...accept scientific answers are inherently provisional...*" and probably most importantly "*see science as a public good with clear demarcations between different interests*". Gaskell (2004) suggests societal goals are a way of implementing good risk leadership, "as *this will develop an appropriate platform that can bring together policy, science and technology, and civil society*", which would need to be implemented through meaningful stakeholder consultations and procedural clarity. However, it should be noted that society is not simply one distinguishable voice; it is diverse and complex; and as such, so are the goals society sets GM regulation.

Chapter Two

General Methodology

2 Chapter Two: General Methodology

2.1 Summary

In order to achieve the research aims set out in chapter one (section 1.2), the stakeholders' perceptions of the environmental risks GM crops pose and their views of regulatory process and appropriate management goals (MG) and assessment endpoints (AE) need to be ascertained. This was achieved through the use of semi-structured interviews undertaken with representatives of each of the stakeholder groups. These interviews were then transcribed, reviewed by the interviewee and then transformed into concept maps ready for analysis. The maps were coded using content analysis in order to identify themes within the stakeholders' responses. These themes were then quantitatively analysed in terms of their importance within each stakeholder group's response and how they differentiated between stakeholder groups.

2.2 Data collection

2.2.1 Standardised or qualitative interviews

Interview data can be collected in both quantitative and qualitative fashions, in the form of standardised or qualitative interviews, respectively. Standardised interviews deal with numerically quantifiable data (responses are categorized), whereas qualitative interviews deal with descriptive texts that can not be easily quantified without losing context (Kvale, 1996; Rubin and Rubin, 1995; Wengraf, 2001). As Strauss and Corbin (1990) asserted, quantitative research can be broadly defined as "*seeking causal determination, prediction and statistical generalisation of findings*"; whereas qualitative research is "*any kind of research that produces findings not arrived at by means of statistical procedures or other means of quantification*".

Standardised interviews (Keats, 2000) would not be appropriate to achieve the specific research objectives of this thesis (Chapter One, section 1.2), as they are too restrictive and thus not allow the breadth of response required. Qualitative

interview , however, "*will allow the interviewee the scope to answer questions to the level required to give their answers context and depth*" (Rubin and Rubin, 1995), while enabling the interviewer the scope to clarify and probe into any areas of interest.

2.2.1.1 Qualitative Interviews

There are three main subdivisions within qualitative interviews, depending on the level of structuring within the interview: structured, semi-structured, and unstructured.

As defined by Rubin and Rubin (1995): a structured interview, *"is one where the interviewer will pose detailed questions to retrieve specific information within a topic area. It limits the interviewee's reposes to a pre-assumed set offered by the interview*"; a semi-structured interview "*is one where the interviewer will pose a question to the interviewee and then lightly guide them by asking specific questions but letting the respondent then shape the rest*"; and an unstructured interview "*is one where the interviewer will pose the broadest of areas under discussion, but will have few specifics in mind; letting the interviewee answer in any way they wish".* To achieve the research objectives, the open yet guided format of a semi-structured interview is most appropriate. It allowed the stakeholders to have freedom of response while enabling the interviewer to direct the responses towards areas of interest (Keats, 2000).

There are two main types of semi-structured interviews (Kvale, 1996): exploratory and hypothesis based. These are determined by the type of information that they aim to gather. Exploratory based semi-structured interviews, explore hypotheses and "*tends to be more open in structure*" (Kvale, 1996). The areas that are required to be covered are put forward by the interviewer and then the interviewee takes it in the directions that they feel appropriate. Whereas hypothesis-testing semi-structured interviews, "*tend to be more structured*" (Kvale, 1996); they tend to focus on specific areas of interest, and often use sets of questions which enable

some conclusions to be drawn and small similarities and differences to be identified.

This research aims to explore broader hypotheses about stakeholders' perceptions of the environmental risks and the regulatory process, rather then to test specific predetermined ones, which would limit the scope of the study. Once the hypotheses have been explored, subsequent studies could be carried out to further test them, a number of which have been the general discussion (Chapter Six).

2.2.2 Stakeholder Identification

The 2002 Earth Summit defined a stakeholder as: "*Those who have an interest in a particular decision, either as individuals or representatives of a group. This includes people who influence a decision, or can influence it, as well as those affected by it.*" (Hemmati, 2002). (Leysen (2003), when discussing the European GMO situation identified the different players (or stakeholders):

- Monsanto and other (biotech) companies involved in the field of Genetic Engineering (GE) (*Industry*)
- The Farmers who are the main consumers of current GM crop products (*Farmers*)
- The Food Industry
- The Supermarkets who have a large voice within the food industry
- The Consumers and the Pressure Groups claiming to represent them (*NGOs*)
- The Scientists (*Scientists*)
- The Politicians (*Government*)

It would be hard to argue that any of these groups is not a stakeholder in the debate, other studies have referred to some, or all, of them as stakeholders in this context (Aerni, 2005; Hall and Martin, 2005). As the aim was to investigate stakeholder perceptions of the environmental implications and the current regulatory process rather then the human health and food related aspects, the

inclusion of supermarkets and the food industry was deemed unnecessary, although it was noted that the supermarkets increasingly focus on the environment as a marketing tool (Kiang, 2006). All of the remaining five groups fit the aforementioned Earth Summit definition of a stakeholder: Whether it be industry or NGOs who have *"an interest in a particular decision"*; scientists and government *"who influence a decision"*; or farmers who are *"affected by it"*. That is not to say NGOs do not influence decisions and government and scientists are not interested or affected by a particular decision. Indeed all five stakeholder groups fulfil almost all aspects of the Earth Summit definition, reaffirming their selection as appropriate stakeholders in the GM debate. Therefore, Leysen's stakeholder groups will be used as the initial basis on which to formulate the stakeholder groups used; further justification can be found in appendix two A, table 2.1.

There is a stakeholder group that has deliberately been left out of this study, despite being heavily relevant in the GM debate; that is wider society, in short the general public. Many arguments can be put forward as to why their inclusion is relevant, (Chapter One, section 1.5.2 & 1.5.7.6). The general public are a wide and multifaceted stakeholder group; to attempt to include a representative section of society's views was too large a venture to be able to do convincingly within this research project. Before making this decision, multiple possibilities were considered.

The first was to use a survey rather than an interview to gauge public opinion to the relevant issues. Whilst it would be impossible to get the relevant representation through interviews, given the time and financial constraints, it could be possible to survey a representative sample of the population in relation to the various questions to be posed in the interview. There were two fundamental issues with this proposed solution to enable a public stakeholder group to be involved:

Firstly, there was the methodological issue of comparing the surveyed stakeholder groups and the interviewed group. Although there are generalised issues with reliability and validity of any qualitative data collection and analysis method, there are also specific issues that need to be addressed for each individual method that would make cross comparisons an issue (Rubin and Rubin, 1995).

Secondly, there is the issue of gaining a representative sample, even with a mass survey, due to poor response rates (Yun, 2000). There is also the possibility of biased results due to self selection where those who are already interested in a topic are more likely to respond than those who are not; a problem cited concerning the GM Nation Survey (DTI, 2003; Poortinga and Pidgeon, 2004). Self selection and response rate bias could affect the demographic spread, with some age, sex and socioeconomic groups more likely to respond then others (Poortinga and Pidgeon, 2004). Due to these issues, and the fact that there have been numerous surveys already done that gauge public interest, like the MORI polls, the GM Nation's Debate and Eurobarometer, (Council of the European Commission, 2001a; DTI, 2003; MORI, 2004), a mass survey was an inappropriate option.

The second option that was considered was the use of a "citizen jury" style approach (Carson and Marlin, 2002; Price, 2000). This is where a cross section of the public is invited in and presented with the facts. In this case it would be: the potential environmental risks, both from opponents' and proponents' positions, and an overview of the current regulatory process. They would then be asked, either individually or as a jury, to make decisions on the issues raised in the interview in relation to what they have heard. Again there are numerous issues with citizens' juries that have to be considered: Firstly, again, there are distinct differences in methodological approach between using a citizens' jury for one stakeholder group and interviewing stakeholder representatives of other groups, which would make comparisons between groups questionable. Secondly, there is the issue with making a citizens' jury demographically representative; numerous juries may be necessary and, as a result, there are then the associated financial and time constraints (Price, 2000). Finally, there is the issue about the extent of

relevant information with which the jury would need to be presented. If the jury methodology is going to be used in conjunction with the stakeholder interviews of other groups, then the information given to the jury needs to be similar to the types and amount of information available to the other groups. As previously discussed, the diverse knowledge possessed by the other stakeholder group members, together with the associated difficulties in producing a representative citizens' jury that was comparable with other stakeholder groups, and the inherent problems in using this methodological approaches, meant that a citizens' jury would not make a suitable and representative stakeholder group. A citizens' jury could be useful in gauging public opinion, not as a direct comparator to the stakeholder group interviews but in conjunction to them. Citizens' juries could be used after the initial stakeholder interviews to see how the public identified with the issues raised by the various stakeholder groups (see the general discussion, Chapter Six). Once the information has been obtained in relation to varying perceptions of the different stakeholder groups aforementioned, then society's views on these stances, using a citizens' jury approach to gain a representative sample, could be potentially beneficial. It might demonstrate why members of society have formed the opinions they have, and which of the stakeholders' views on particular aspects they related to most. This is a potential interesting direction for future work.

The final way of producing a societal stakeholder group was through the use of public interest organisations. These organisations act on behalf of the public's interest, by utilising consensus surveying and raising specific public concerns (e.g. consumer watchdog associations) or by shared belief in the issues and the causes the organisation supports, via public subscription, like the non-governmental organisations or national unions. The issue here is that, to a certain extent, this is already being covered in the NGO stakeholder group anyway and therefore the need for an additional stakeholder group is questionable or even invalid. There is also a relevant question as to whether public interest groups voice the concerns of society or those of a vocal and active few (Marris, 2001); this is certainly a criticism some would make of NGOs (Chapter One, section 1.6.5.2). Partly due to the issue of whether public interest groups would produce a genuine sample of society's views, and also partly because if they would, then these views are

already accounted for, to an extent, by the NGO stakeholder group, the inclusion of a sixth stakeholder group, comprising public interest groups, was not a logical option either. Public opinion should be incorporated in future studies resulting from the findings of this project (Chapter Six). Thus, this section concludes that whilst public opinion does have a place in both the regulatory system and the potential risk associated with GM crops, it would be almost impossible to produce a robust enough way of incorporating a public interest stakeholder group without reducing the integrity of the rest of the project, once temporal and financial constraints on this project are taken into account.

There will then be five stakeholder groups whose perception of the potential environmental risks, the current regulatory system, as well as the potential management goals they would like to see driving the regulatory process, will be gauged through the use and analysis of an open-ended semi-structured interview (section 2.2.1)

2.2.2.1 Stakeholder representation within each group

The next step is the selection of the relevant stakeholder representatives to be included in each group. Some groups would invariably be more difficult to select representatives for than others, and undoubtedly no selection method is 100% infallible.

The number of representatives that should be interviewed within each stakeholder group is a contentious issue; ideally it should be as many as possible within the time and financial constraints. An eighteen month period (October 2004- April 2006) was set, within which time interviews with as many stakeholder group representatives as possible were lined up. Some groups required a greater number of respondents than others, to get representation across the group. When deciding the spread of representatives across a stakeholder group, there were numerous considerations which needed to be taken on board:

Firstly, in the scientific stakeholder group, for example, the representative spread could be considered across a number of independent variables: scientific training; level of qualification, familiarity with either biotechnology or agricultural production. There would be no really right or wrong method of choosing the independent variables to use, when considering the representative spread. It would come down more to levels of appropriateness, when considering what would be required from the stakeholder group in question. The independent variables that would have to be considered in the selection, repeated for each stakeholder group, along with justification for use of the variable, is discussed in table 2.2 (appendix two A).

Secondly, there is the issue of independence of the stakeholder representative. Independence of variables is a critical factor when determining the types of statistical test available for utilization; statistical confirmation of trends is not central to this investigation, however, statistical tests will be used when appropriate and can be applied to interdependent data sets. The question is whether, in a predominantly qualitative study, the potential interrelatedness of the stakeholder groups will have a detrimental effect in achieving the research aims set out.

When considering which stakeholder representatives to select, the first thing that required deliberation was whether the representatives should be selected randomly or whether a predetermined criterion for selection should be made. Familiarity with the debate was important as this study was designed to assess stakeholders' perceptions of two *specific* elements within the debate: the potential environmental risks and the current regulatory system. With the latter, especially, there needs to be a certain amount of exposure of the representatives selected to the debate, for the stakeholders to really feel able to answer questions about these issues. When considering the stakeholder groups in relation to a central issue like familiarity with the GM debate, the stakeholder groups became more interdependent than initially presumed, as there were definite overlaps between the various groups. Stakeholders, who were obvious first choices for a certain groups due to their active discourse and familiarity within the debate, often fell into these

overlaps. For example there were: academic scientists researching GM crops who had had roles on scientific advisory committees: industry regulators who had previously been government regulators; NGO representatives who had farming commitments. It was practically impossible to have no blurring of the edges of the groups when considering familiarity with the debate as the most important variable. This left two potential scenarios, (depicted in figures 2.1a and 2.1b):

Familiarity with the GM debate

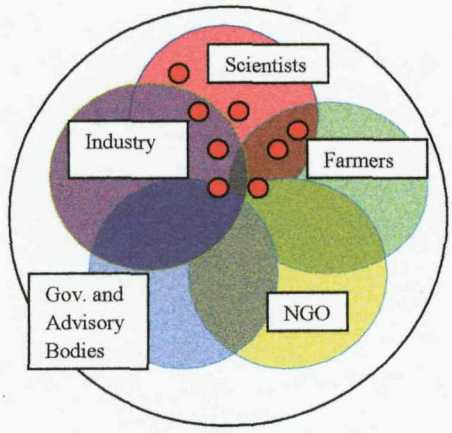


Figure 2.1a: The stakeholder groups are depicted in the context of familiarity. Clear overlaps can be seen at the fringes of each group; potentially with all other groups (the groups have been given different colours to demonstrate this. Representatives just for the scientific stakeholder group (to aid in clarity) are depicted by the red circles, illustrating the potential for this group to overlap with others.

Independent Stakeholder Groups

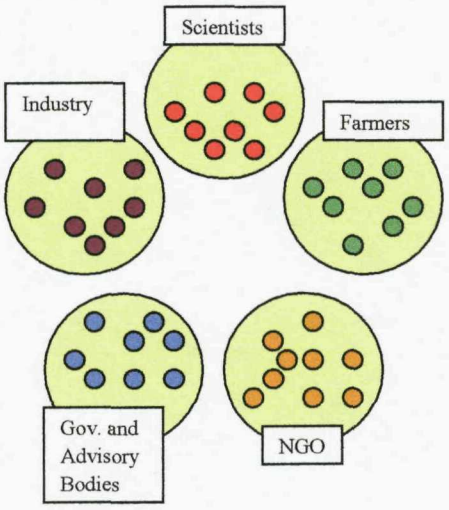


Figure 2.1b: The stakeholder groups are depicted in the context of independence. Selection will be made based on a representatives independence form all other stakeholder groups bar the one they are representing.

The first option was to accept there were overlaps between the stakeholders groups when chosen based on their familiarity with the debate. To try and address the issue that some stakeholders might have links to other groups, stakeholders were chosen to represent one group due to their primary expertise, their representation of a particular stakeholder group was made apparent to them, both prior and during the interview. Attempts would then have to be made, to address any issues that could come from stakeholder groups merging, due to choice of representatives.

The second option was to consider the stakeholder groups' and representatives' independence as the key factor and therefore only select stakeholders that could be clearly categorised as belonging to a specific stakeholder group. This would limit the number of potential representatives available for selection and might result in the selection of a less appropriate of representatives.

Since stakeholder knowledge about the debate was paramount, familiarity was considered more important than stakeholder group independence. Indeed for some of the stakeholder groups', independence would have been near impossible as all the potential representatives were linked to, in some ways one of the other stakeholder groups. The first scenario depicted in figure 2.1a was chosen, i.e. to accept that the stakeholder groups were not totally independent of one another when looking at them in the context of representative familiarity to the GM debate. Attempts to address the issue of interdependence of the representatives to a number of stakeholder groups were made to enable the stakeholder groups to be as independent as possible. Representatives were chosen within each stakeholder group, being mindful not to load the stakeholder group with individuals who might have links to one of the other stakeholder groups. For example, one of the main links to another stakeholder group, found with potential representatives of the scientific stakeholder group, is that a number have participated in governmental advisory committees, due to their associated scientific expertise. Therefore, when potential representatives were considered for the scientific stakeholder, it was important to make sure it was not overloaded with scientists who had been on advisory committees. This is not to say that participation on advisory committees meant the representative was ruled out (as would have been the case if the methodology followed was that in scenario two, figure 2.1b). The second way this issue was approached was when the potential representatives were contacted; in the initial letter, which went out to all the stakeholders (appendix two B), it was clearly outlined that, due to their current role or position as X, they were being selected to represent the view of a particular stakeholder group. This specified to the interviewee the role that they had been chosen to represent and this was reiterated during the interview. These two methods of addressing the issue of representative independence are by no means above criticism. They do however go some way in addressing stakeholder interdependence and enabling study to get as even a spread across each stakeholder group as possible in order to get as broad a spread representation as possible, while taking into account the financial and time constraints. In total, forty six stakeholders took part in this study, seven of which were involved in the

piloting stage. The remaining thirty nine stakeholders were made up of: ten farmers, five industry representatives, seven government or advisory body representatives, eight members of non-governmental organisations and nine scientists.

2.2.3 Interview Production

2.2.3.1 Transforming the research aims into interview questions

As the research question dictates the data derived from the interview, the data sought needs to drive the question formation. A number of authors suggest a research guide (Keats, 2000; Kvale, 1996; Oppenheim, 1992; Wengraf, 2001) as a way to ensure this is the case. These help to focus on desirable achievements and how things can and should be asked (Wengraf, 2001), i.e. how the research aims are translated into research questions. When formulating the interview questions, it is advised by Kvale (1996) to form two guides: one with the project's main thematic research questions (research aims), the other which covers the questions which are desired to be posed during the interview.

There are essentially three research aims (Chapter One, section 1.2), this study wishes to achieve: firstly, to assess different stakeholders' perception of the environmental risks associated with the deliberate release of GM crops; secondly, to assess different stakeholders' perceptions of the current regulatory process governing the deliberate release of GM crops; and finally, to identify management goals and assessment endpoints; these then could be used as drivers of the current regulatory process in order to identify stakeholders concerns. These clearly need to be dealt with in separate sections of the interview. While the first and second research aims have a number of facets upon which they can be investigated (table 2.1), the final aim is more direct and very much stakeholder response driven, and as such it is less open to pre-determined questions.

The facets of the first two research aims identified in table 2.1, were the basis for the formation of the interview questions in their respective sections. For research aim three, one broad over-arching question about stakeholder identification of management goals or assessments formed the basis of the research sections. Further probing questions were used to teased apart stakeholder responses and provide clarification as to the goals or endpoints required. It should be noted that the generation of the interview questions was not a simple task. In total it took 2 ½ months to finalise the questions. During this time there were numerous rounds of deliberation as to the wording (in order not to lead the respondents), the length, the scientific content, and the amount of questions, to name by a few. Advise was sought not only from project supervisors but also others working in the area (Ely, 2005). Two rounds of piloting the questions were also undertaken in order to assess both the appropriateness of the individual questions and the interview format as a whole. The first round brought a number of issues to attention; these included the removal of a number of terms familiar to the scientists involved in the debate but not well understood by those outside of that (including scientists). The length of the interview was also shortened as a result of this first round of piloting; as a result a number of questions were dropped in order for more time to be allowed for the key questions (section 2.2.3.2-2.2.3.4). The second round of piloting identified far fewer issues as would be expected. No major changes were made to either the interview as a whole, or specific questions.

Table 2.1: The facets upon which research aims one and two can be investigated

Research Aim One	**Research Aim Two**
To gauge the stakeholders: • Environmental concerns over the deliberate release of GM crops in general; • Environmental concerns in relation to specific issues: o gene flow; o non-target effects; o Potential alterations to farm management practices.	To gauge the stakeholders: • Views of the current regulatory process; • Views of the scope of the current regulatory process; • Views of the review process an application for deliberate release has to undergo; • Views on whether there is any aspect of the regulatory process which could be improved.

2.2.3.2 *Research aim one (RA1)*

Research aim one sets out to identify the stakeholder's environmental concerns in relation to the deliberate release of GM crops. Clearly the first thing which needed to be identified was the general concerns stakeholders hold in relation to the environmental implications. Like all the subsequent research aims, it will begin with a broad overarching question (RA1a) which reiterates the initial aim:

RA1a:"*Do you have any environmental concerns over the deliberate release of GM crops?*"

Once the general questions have been asked, there are some specific environmental concerns, which have been identified in the current regulatory process (Council of the European Commission, 2001b) (table 2.1). These include gene flow, non-target effects and potential alterations to farm management practices (see Chapter One, section 1.4.2-1.4.4). These form the basis of the scientific assessment undertaken as part of the notification dossier (see Chapter One, section 1.5.1). It would be of value, therefore, to see how different stakeholder groups identified with these issues, as this might affect their subsequent views of the regulatory process. Stakeholders' opinions toward gene flow issues, non-target effect issues and alterations to farm management issues are addressed in the follow questions (RA1ba, RA1bc and RA1bd, respectively). It should be noted that the numbering of research questions sometimes does not follow a logical progression. This is due to the fact that in the initial interview there were more questions asked, however not all have been used for a variety of reasons. It was felt that it would be better in terms of continuity to keep the initial numbering of the questions, rather than renumber them. This is because, although not all the questions, and responses, were used in this thesis they may be used in subsequent papers. By keeping all the numbering of questions consistent it will aid anyone cross-referencing future papers with the thesis.

RA1ba: *Among the scientific concerns which have been raised, include issues of gene flow, what are your feelings about the potential risks gene flow might pose?*"

RA1bc: "*Among the scientific concerns which have been raised, include issues of non-target organisms, what are your feelings about the potential risks posed to non-target organisms?*"

RA1bd: "*Among the scientific concerns which have been raised, include issues of potentially altering farm management practices, what are your feelings about the potential risks alterations to farm management practices might pose?*"

2.2.3.3 Research aim two (RA2)

RA2 sets out to identify the stakeholders' perceptions of the current regulatory process; like RA1 it starts with a general introductory question to elucidate what the stakeholders' concerns are (RA2a):

RA2a: "*What are your thoughts on the current regulatory process legislating the deliberate release of genetically modified crops?*"

There are two aspects of the regulatory process which have caused great debate in the literature (see Chapter One, section 1.6.2): firstly, the scope of the regulatory process, in terms of the questions it asks and, secondly, the way in which a notification for deliberate release is reviewed by expert bodies. Gauging stakeholders' opinion of both the scope and the review process might give insight into the issue of regulating GM crops; this will be addressed by questions RA2ba and RA2bb:

RA2ba: "*What are your thoughts about the scope of the current regulatory process?*"

RA2bb: "*What are your thoughts about the current review process an application for release has to undergo before an application is approved?*"

Finally it would be useful to determine whether the stakeholders can identify improvements that could be made to the current process to address some of their concerns. If they can, this might provide insights into ways in which the regulatory process could be improved to address a wider set of stakeholders' concerns. RA2bd aims to address this:

RA2bd: "*Are there any aspects of the current risk assessment process which, in your opinion, have room for improvement?*"

2.2.3.4 *Research aim three (RA3)*

RA3 sets out to identify any MG or AE they would like to see driving the regulatory process in order for it to address some of the concerns they have identified:

RA3a: "*Are there any additional management goals or assessment endpoint which you would like to see addressing some of the issues or concern you have raised?*"

2.2.3.5 *Introducing and closing the interview*

A number of authors (Keats, 2000; Oppenheim, 1992; Rubin and Rubin, 1995) discuss the importance of introducing the subject (interviewee) to the research prior to delivering the main research questions. This can be done through using an introductory paragraph, which introduces the interviewer, the work being conducted and the overall aims of the interview. By setting out what is required from the interviewee in terms of time, responses and how the interview is going to run, the introductory paragraph will also aid the interviewer and interviewee by easing both into the process (Keats, 2000; Oppenheim, 1992; Rubin and Rubin, 1995). This is important as both the interviewer and interviewee may be nervous (Keats, 2000),. As with the initial contact letter sent to potential respondents (section 2.1.4.1), the key to a good introductory passage is to present the right amount of relevant information without losing the interest of the respondent. Indeed a lot of the information in the introductory passage will revisit what was discussed in the initial contact letter, to reinforce the key aims of the research, the reason for selecting the respondent for the study, and the requirements placed upon the respondent. The introductory paragraph can be seen in appendix two B.

To ease the respondent into the interview, it is more appropriate to begin with a question series gauging some relevant information about respondent in terms of their background, rather then start on one of the main research aim question series (which are often more taxing) (Wengraf, 2001). Therefore the first series of questions asked the interviewee to provide background information about themselves in relation to their work history and links to the GM debate: "*Could*

you give me an overview of your role in your current position as X?"; "*Could you give me a brief overview of your work history?*"; "*Could you give me a brief overview of the role you have had in the GM debate?*"; "*Are you interested or involved in any activity, outside of work, relating to: science, the environment, or farming?*"

After the introductory paragraph and question series gaining background information, the three question series coving the research aims was asked. On completion of these, rather then just finishing the interview, an interview closing question series was suggested (Kvale, 1996; Oppenheim, 1992; Wengraf, 2001). This enabled the interviewee and interviewer to "wind down" (Rubin and Rubin, 1995) and the interviewer to make sure that the interviewee was aware of just how valuable their contribution was. The simplest way of achieving this was by asking whether the interviewee has anything they wish to discuss that had not been covered by the interview:

"*The interview has nearly drawn to a close, thank you very much again for your time. I would like to finally ask you whether there was anything that we have not covered in the interview that you felt we should or would have?*"

It should be noted that while the closing series is aimed at slowly stopping the interview, it is not any less important, indeed as Oppenheim (1992) and Rubin and Rubin (1995) state, a lot of key information often comes at the closing stages of an interview. In the second round of pilot interviews, none of the respondents (one representative from each of the stakeholder groups) identified any additional issues they wanted to address. Indeed 3/5 complimented the thoroughness of the interview.

2.2.3.6 Ensuring validity and reliability of the data collected

The key to ensuring the data collected is of the highest reliability, and as a result valid, is to make sure the data is collected in a way that reduces subjectivity (Kvale, 1996; Wengraf, 2001), as objectivity is a key component for ensuring the reliability and also validity of the data collected. The issue with qualitative data,

and in particular semi-structured interviews, is that it is, to an extent, their subjectivity that gives the data collected depth and richness. A sensible compromise needs to be found between improving objectivity to gain validity, and ensuring the positive subjective qualities are conserved.

Many researchers in this field have stated that if semi-structured interviews are methodologically planned and carefully executed, then there should be no reason why they should be questioned as a scientific research method on face value (Keats, 2000; Oppenheim, 1992; Rubin and Rubin, 1995). The key is to methodologically plan to reduce additional sources of subjectivity, which can reduce both the reliability and validity of data collected. The two rounds of pilot interviews, as already mentioned (section 2.2.3.1), helped identified areas of subjectivity. Sources of subjectivity resulting from the researcher or the respondent, rather then those inherent in the methodology, need to be addressed and these will be discussed in more detail in the following section.

2.2.3.6.1 Researcher associated subjectivity

A concern is that bias as a result of the researcher's agenda could compromise the data collection. Researchers will have some preconceived ideas of what they expect to see from the data. There is a concern that they could manipulate the data (perhaps subconsciously) so that it shows what is expected rather then what is true (Wengraf, 2001). This is not an issue that is solely related to semi-structured interviews or even qualitative data studies, however, it is one which needs to be addressed.

Generalised interview formats across stakeholder groups, and internal and external reviews of questions that aided in reducing researcher bias and resulted in the removal of loaded and leading questions, also reduced routes of researcher bias (Kvale, 1996). Internal reviewers from both academia and industry were used to test the robustness and reliability of the questions. The internal review was tremendously useful, it identified gaps in the original interview and also provided

reworked question which reduced bias resulting from loaded or leading questions. External reviews were also undertaken and this was done via the pilot studies and by the interviewees themselves. Once the interview was transcribed, it was sent to the interviewee for them to review, by reviewing their responses at a later date, it improves temporal reliability. The key ways to ensure the methodology remains as objective as possible is to make sure the methodological approach is consistent between and within the interviews. A number of steps were taken to ensure this:

- A standardised set of interview questions and interview format
- Question prompts, when and if required, came from a standardised prompt sheet
- All written communications to stakeholders, (initial contact letters and follow up letters), were standardised

2.2.3.6.2 Respondent bias

Respondents as well as researchers can introduce bias and affect the objectivity of a study (Wengraf, 2001). The most common form is prestige bias, which results from a reluctance to admit a lack of knowledge (De Vaus, 2002; Kvale, 1996; Oppenheim, 1992). This can be for self motivation or due to a sense, or feeling of needing to provide, the interviewer with information (De Vaus, 2002; Oppenheim, 1992). While the literature says that there are no simple fixes to the issues associated with prestige bias; good self-checks, briefing schemes for respondents and piloting schemes will help to combat them (Kvale, 1996; Oppenheim, 1992). Briefing schemes were incorporated in both the introductory paragraph and the initial letter. Respondents were made aware that it is their attitudes and opinions which are of interest to this study, and as such there are no right or wrong answers. Emphasis was placed on the importance of the accuracy of individuals' views. Piloting were also utilised to identify questions prone to stakeholder bias, although none were obviously apparent.

2.2.4 Interview procedure

2.2.4.1 Initial letter

Each potential interviewee was contacted initially via a letter (appendix two B), informing them about the study and its research aims, identifying why they had been selected as a key representative of a specific stakeholder group and asking whether they would be prepared to participate.

There are some crucial guidelines to adhere to when producing a preliminary letter which are identified in almost all the literature (Keats, 2000; Kvale, 1996; Oppenheim, 1992; Wengraf, 2001). To enable the potential respondents to feel they understand what they are agreeing to, the preliminary letter needs to: cover all the aspects that the work involves (this includes: the research aims, the role of the respondents in relation to these research aims, what will be required of the respondents in terms of time and information, and how the data obtained from the respondents will be utilised); it cannot however be too long or there is the risk that the respondents might lose interest or focus. Thus the initial preliminary letter needs to be pitched at the correct level in order to capture the respondents' interest in the study without patronising or boring them. The broad range of stakeholders makes this a challenging task. The letter needs to be pitched at a level to ensure those without a scientific background, understand the scientific elements of the study and what will be required from the respondents; however this needs to be put in such a way that those with a scientific background are not patronised by the content.

One potential way of addressing this was to send different letters to the various stakeholder groups pitched more specifically at the respondents. The inherent problem with this method was that it would introduce informational bias into the study (De Vaus, 2002; Wengraf, 2001). Different stakeholders would have been exposed to different information and thus potentially could be participating in the study under different premises. Thus a single letter was decided upon, which would be pitched at a level all the stakeholders could identify with. This decision

was made because the loss of one or two potential respondents due to inadequate pitching of the preliminary letter was considered to impact on the study to a lesser extent, then the potential bias that could be incurred through individualised letters. Specific scientific details which could have been an issue in a generalised letter were left out; instead there was the option for those who wanted to know more about the study prior to their participation to contact the interviewer directly. It should be noted that none of the potential respondents took up this opportunity. Also of the fifty letters sent out, only six respondents declined to participate, two of them suggested replacements that made up the final fifty. Thus any potential negative effect the pitching of the letter had seemed to have, had little effect on respondents' willingness to take part in the final study numbers.

2.2.4.2 Interview protocol

Once the potential respondents had confirmed their involvement in the study, an interview date and location was set. A number of studies discuss the importance of the interview setting, with respondents normally performing better in familiar surroundings (Keats, 2000; Kvale, 1996; Wengraf, 2001). Interviews were therefore arranged to be in the work places of the respondents; respondents were also given a list of potential dates and time, enabling respondents to choose a time best suited for them.

The interview itself was recorded, this enabled the interviewer the freedom to ask questions and probe responses without being concerned about dictating the interview. Two recording devices, a Sony digital Dictaphone and a Sharpe Mini-disk player were used. During the introductory passage, the respondent (now to be referred to as the interviewee) were made aware of the recording devices and asked to sign a consent form enabling the interview to be recorded (appendix two B). The consent form did not hand over consent to the interviewer to use the interview, only to record the interview and remove it from the interviewee's possession to transcribe it. A second consent form was sent with a copy of the transcript to gain consent for the use of the interview (section 2.3.1). Once the interviewee had signed the consent form, then the interview began.

The interview question series were read in sequence, and within each series the broader questions were asked prior to the specific ones (section 2.2.3.1). Interviewees were allowed to spend as little or as much time in answering a question as they wanted. The interviewer's contribution was minimised to the extent that the interviewer only asked specific questions or clarified points raised the interviewees. The interviews varied in length; while they were predicted to last an hour, some were over in around 30 minutes while others lasted for almost 3 hours. The differences in time were very much driven by the interviewee; some were much more concise in their answers than others. There were also interviewee-driven time constraints; some had other arrangements which impinged on the time they could spend on the interview. In a number of cases (8/50) this affected the number of interview questions that could be asked, which was undesirable but also unavoidable.

2.3 Data preparation

2.3.1 Transcription procedure

There are many ways in which a qualitative interview can be transcribed (Oppenheim, 1992). For this study a direct transcription of the recorded interview was selected. The main reason was to ensure validity of the data collection process (De Vaus, 2002); by transcribing *verbatim* the interview, rather then using other methods which transcribe only certain selected text, there is no room for researcher bias in text selection. This method is however more time consuming, with a number of authors suggesting transcription often takes several times the amount of time taken to record the interview (Lacey and Gerrish, 2006). This was demonstrated in this study, where the total interview time was 41 hours and 7 minutes, the initial transcription time (time taken to get the first draft of the transcript from the recording, prior to re-listen and read through and any additions from the interviewees) was 385 hours, about nine times that of the interviews. Interview questions were made distinguishable from the interviewee's response by being placed in italics, both were in size 12 font. Each paragraph of the transcript was numbered, as a way of identifying the text. Numbering paragraphs were

chosen over numbering individual lines as line numbering is often sensitive to formatting (Keats, 2000; Oppenheim, 1992). Prior to returning to the interviewees, the transcripts went through two rounds of proof reading to ensure they were direct replicates of the recorded interview.

There were numerous reasons for sending the transcripts back to the interviewee: Firstly, by allowing the interviewee to review the transcript prior to giving their consent for the interview to be used in the study, it gave the interviewee increased confidence in participating. It was hoped that this confidence would also give them greater freedom to express their points, as they would feel that they had a "safety net" after the interview to review their comments. Secondly, since interviewees' reviewed the transcript, it gave them the option to add more detail into their response if and when required. This added to the contextual depth of the interview. Finally, it is a form of validation that is second to none (Keats, 2000). The interviewees can self-validate that the transcript is an accurate representation of their attitudes and opinions. It also provides a way of bolstering the temporal validity of the interviewee, as the interviewee is reviewing and essentially reconfirming their opinion at a later date. The lack of temporal reliability of many qualitative studies is something which is often criticised (Wengraf, 2001).

The transcript, along with a cover letter and second consent form (appendix two B), was sent to the interviewee. The cover letter, as well as expressing gratitude for their participation in the study, outlined the time frame in which the interviewee had to review the transcript, the issue of anonymity and contact details in the event the interviewee needed more information. In terms of time frame the interviewee was given a month to review and return the transcript, a reminder letter was sent out one week prior to the deadline to remind interviewees of this fact. If the transcript was not returned, automatic consent was assumed and this was outlined in the initial transcript consent letter and reminder letter.

Interviewees were given three options in relation to anonymity: Firstly, to give full consent and to letting their name be used. Secondly, to give full consent, while remaining anonymous. Finally, to give full consent assuming a number of stipulations were met. Interestingly, the majority of interviewees gave full consent but required anonymity, only five stipulated further requirements. Because of the high numbers requiring anonymity, it was felt all interviews should be anonymous. The reasoning behind this was that in some stakeholder groups there were only a handful of stakeholders with the right expertise, if one or two wished to remain anonymous while others were named, it would make identifying the anonymous respondents easier. Thus, for the sake of those who wished to remain anonymous, all interviews were coded. Representatives became Scientist A (SA), B (SB), and so on; these codes were used for quotations in the results chapters.

Once the reviewed interviews were returned, a second phase of transcription began, this time making the initial transcripts (pre-review) T0 into post-review transcriptions T1, which included any amendments or additions the interviewee made. The majority of interviewees didn't make any additional comments, although they did make amendments to the transcript. The majority of amendments were an artefact of the transcription process, that is, as the initial transcription was a verbatim word for word copy of the recording, a number of interviewees were sometimes surprised at their grammar. This is because written English is very different to spoken English in terms of grammar and the way ideas and thoughts are formed. As a result a number of interviewees attempted to alter the interview in an attempt to improve the grammatical context, the content however remained constant.

2.3.2 Conceptual maps

Once the T1 transcripts were produced, they were then converted into concept maps. A conceptual map is a collection of ideas (concepts) and the relationships between concepts arranged in the form of a map (Eden and Ackermann, 1998; Eden and Ackermann, 2004; Eden et al., 1992; Williams et al., 2003). Graphical representation of concepts and their relationships into conceptual maps can facilitate data analysis in a number of ways (Shaw et al., 2003), elucidating

previously undiscovered connections between concepts and identify potential underlying themes and issues (Eden and Ackermann, 2001; Eden and Ackermann, 2004; Williams et al., 2003). Conceptual maps are a well established technique in elucidating themes from interview text (Weick, 1995) and have been applied in a multitude of ways to address different research problems across several research disciplines, including: political research, policy management, environmental planning and operational research (Eden and Ackermann, 1998; Eden and Ackermann, 2004; Hjortso et al., 2005; Shaw et al., 2003). Some of the suggested areas of use include: "*interview analysis; risk identification; qualitative data analysis; stakeholder analysis*" (Brightman, 2004), implying that it is an ideal form of analysis for addressing the research aims set in this project. The production of concept maps enables conceptual models to be formed, breaking done the stakeholder response into a series of concepts (sentences) which can then be coded according to the underlying themes they represent (section 2.4.2). The links between concepts express relationships (Williams et al., 2003); there are many different forms of potential relationship between concepts, of which causal and connotative are the most widely used (Eden and Ackermann, 1998). This study focuses on causal relationship, which are "*when one concepts leads to another or affects it in some* way" (Brightman, 2004). Causal relationships are illustrated with an arrow, pointing in the direction of the causal effect. In the maps generated from the stakeholders' interviews most arrows will point chronologically, from the first point made by the interviewee to the next point; showing the construction of ideas from individual sentences. However, in the case of showing the relationship between a statement and the justification (an example of a statement made) the arrow would point from the justification to the statement.

Nine conceptual maps were produced for each interview, relating to each of the research questions (section 2.2.3.2-1.1.3.4). The initial maps were produced directly from the T1 version of the transcript. Each concept within the map was derived by taking a sentence from the interview (reasoning for this is discussed in section 2.4.2). Sentences were determined by delineators such as: full-stops, colons, semi-colons, exclamation marks, question marks, and certain words which are used to join two sentences (but, and, because, however). Thus, in essence the

maps were simply a coded version of the initial transcript. To distinguish between the interviewer and stakeholder responses, the initial research question posed by the interviewee was written in italics and situated on a blue back ground, the stakeholder's response were situated on a yellow background. Concepts were then grouped, in order to form sets; these were used to distinguish between different themes identified by the stakeholder in relation to a singular research question. This was performed using content analysis (section 2.4.1) a standard analytical method from which conceptual maps stem (Axelrod, 1976). By identifying clusters of themes both simple and complex, statistical analysis could be used to identify key elements (Eden and Ackermann, 1998) (section 2.4.3).

2.4 Data analysis

2.4.1 Content analysis

There are numerous methodological options available for analysing the content of qualitative data sets. These include: rhetorical analysis, discourse analysis, structuralist analysis and interpretative analysis. A summation of each, adapted from Neuendorf (2002), can be found in table 2.3 (appendix two A). There are various advantages and disadvantages associated with each methodology, as each sets out to address a different aspect of content in the text. Content analysis is the most appropriate form to use to address the research aims set out in this study: Firstly, it is an umbrella term, used to describe multiple quantitative and qualitative techniques, which can be used in conjunction to support one another. This enables statistical generalisations to be made from qualitative data sets and then for these statistics to be placed back into the context from which they were derived. This combination of what are generally considered as antithetical modes of analysis means that good content analysis utilizes the strengths of both in combination; this triangulation of methods, "*strengthens the research in terms of the validity of conclusion, when mutual confirmation of results can be demonstrated*" (Neuendorf, 2002). Secondly, it can be used directly on transcripts of human conversation and therefore the loss of contextual depth associated with data transformation is reduced. Coding is still a fundamental aspect of context analysis, however, preliminary analysis techniques, used in context analysis, can

be done on raw data sets. The coding used in content analysis also tends to be sympathetic to the context of the initial data set and is therefore truer to the initial transcript.

Content analysis is the systematic, objective, quantitative analysis of message characteristics. "*... a research methodology that uses a set of procedures to make valid inferences from text,* (Weber, 1990). There have been numerous definitions of content analysis produced, which have been adapted over time: *"Content analysis is any research technique for making inferences by systematically and objectively identifying specified characteristics within text"* (Stone et al., 1966) ; "*Content analysis is a research technique for making replicable and valid inferences from data to their context* [institutional, societal and cultural]" (Krippendorf, 1980); "*Content analysis is a summarizing, a quantitative analysis of messages that relies on the scientific method (including attention to objectivity-intersubjectivity, a priori design, reliability, validity, ability to make generalisations, and hypothesis testing) and is not limited as to the types of variables that may be measured or the context in which the messages are created or presented in*" (Neuendorf, 2002).

According to Bird (1998), and Klee (1997), what differentiates content analysis from other, more qualitative or interpretive message analysis, is the attempts to meet the standards of scientific method, fulfilling what is required while enabling it to fit within the positivism paradigm of social research. Berelson (1952), identified many applications for context analysis; two in particularly apply to this study: firstly, "*the use of content analysis to code open-ended questions in surveys* [or indeed interviews]"; and secondly, "*to reveal the focus of individual, group, institutional or societal attention*". The central theme in content analysis is the identification of categories from the initial text. Classification into categories is often based on similarity of meaning, whether this similarity is:

Words with different meanings or connotation that co-vary empirically (inferred categories);

or:

Words with similar meanings or connotations that do not co-vary (assumed categories)

There is however much debate over which classification scheme should be used (refer to Weber, (1990); Neuendorf, (2002)) and both are justifiable to their advocates. For this research, assumed categories were used predominantly, as this study aims to identify various stakeholders' perceptions to key issues or themes. These issues and themes might be conveyed differently, in terms of the linguistics used, however the meanings of these words will be similar and are therefore unlike to co-vary.

By coding and categorising the text, the interviews can then be compared, both in terms of frequency of words, categories or themes, as well as the interrelationship between categories and themes. As Neuendorf (2002) quotes from a personal communication with Fink (1999 [March, 26]), "*the goal of any quantitative analysis is to produce counts of key categories and measurements of the amounts of other variables*". Common approaches to content analysis are often categorized as descriptive, inferential, psychometric; and predictive, these are discussed briefly in table 2. 4 (appendix two A)

Descriptive content analysis will be used in this study to identify stakeholders' views towards: environmental risks posed by the deliberate release of GM crops, the current regulatory process, and potential management goals and assessment endpoints. Inferential content analysis will be used, in part, to explain any differences between the stakeholders' descriptive content analysis identifies.

2.4.1.1 Ensuring validity and reliability of the content analysis

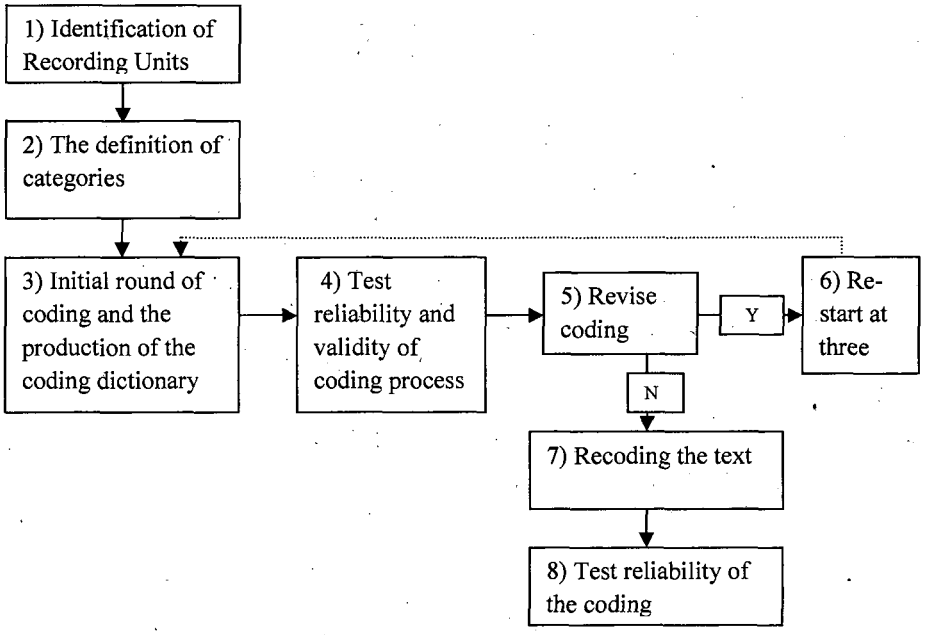
As with all analysis techniques, the reliability, validity and to a lesser extent to which generalisations can be made is central to the strength the conclusions drawn from it, "*The central problems of content analysis originates mainly in the data*

reduction process by which many words of text are classified into much fewer content categories" (Weber, 1990). With content analysis, both reliability and validity problems usually grow out of the ambiguity of word meanings, category definition and/or coding rules. The methodological procedure surrounding the formation and utilization of the coding dictionary will be central to this (section 2.4.2).

2.4.2 Data coding and the formation of the coding dictionary

There are three main stages involved with coding text (De Vaus, 2002; Krippendorf, 1980); these stages are not independent, rather they are iterative. They are dealt with independently here in order to maintain clarity of discussion. The stages are: defining the research topic in terms of categories, identifying the units of content to be classified and the enumeration system (category counting). The first two are part of a process termed the coding procedure, whilst the latter is done after coding commences but needs to be considered prior to designing the coding system, although it need not be fully developed. Many authors (Krippendorf, 1980; Neuendorf, 2002; Weber, 1990) describe the coding process as involving a number of steps, outlined below (figure 2.2). By following this step-by-step procedure a methodological approach is formed, which can then be repeated as well as tested for reliability and validity.

Figure 2.2: The eight steps of the coding process



2.4.2.1 *The identification of the recording units (units of content)*

The recording unit is the designated unit within the text to be coded; there are five types of unit available: single word (word sense), theme, sentence or paragraph, character, and whole text. Using whole text or characters would be inappropriate for this study as neither enable the context of the response to be evaluated. "*Single words are often used as they improve reliability, they are useful when trying to identify how key issues are placed in the text... improvements in computer programs has resulted in word coding being much more time and cost effective"(Holsti, 1969)*. The issue with using single words is that there needs to already be preconceived ideas about which words to select prior to the analysis; as a result key themes or issues which are present in the text but are not preconceived might not be identified. Using preconceived themes is also subject to the same issues as single words; selecting only subject verbs and objects as the recording units when producing the initial maps reduces the text used, this could loose some of the contextual depth of the interview. The identification of themes through coding (categorisation) of the data rather then limiting the recording units is a more appropriate solution. Thus sentences were used to fulfil the research aims set, they enable the whole transcript to be analysed rather then selecting preconceived themes or key words.

2.4.2.2 *The selection and definition of categories*

There are numerous ways to categorise data; when deciding upon categories, there are five underlying principles category selection should adhere to:

1) They should be reflective of the research purpose. That is, they should link back to the initial research questions whilst clearly showing how the data fits into the category, and therefore how it relates back to the research questions. Holsti (1969) suggests an operational definition, which satisfies the two requirement, "*categories are a valid representation of the analysts concepts, and are sufficiently precise that they guide the coders to produce reliable judgements*".
2) They should be exhaustive, thus all the relevant data is classifiable into the chosen categories,(Weber, 1990). One way of ensuring all the relevant categories are included is to make sure that the initial research concept is clearly defined, this makes category classification clearer. Re-coding of the data sets will also improve this. The initial coding will identify all the data needing categorising and so should therefore identify the categories required. The subsequent coding will ensure that the data is placed in the correct category, as some categories will only be identified after the initial data sets are coded.
3) They should be mutually exclusive, that is, data should only fit into one category or subcategory, (Holsti, 1969; Weber, 1990). Clear definitions of the categories, as well as decision trees, will aid this as it will enable researcher to have a clear methodological process to follow.
4) Classification of data into categories should be independent, (Holsti, 1969) that is, the classification of one piece of data should not effect subsequent data classification.
5) Categories should be of a single class, that is, categories such as: positive, negative, scientific, non-scientific should not be pitted against one another. Rather they should be subcategories of one another i.e. scientific-positive, scientific-negative, non-scientific-positive, and non-scientific-negative.

The initial step is the selection of the categories; there are many possible schemes available to the researcher for classifying content data. Category schemes include:

value based, traits, verbal interaction, subject matter, directional, evidence based, and ends and means. The latter four forms will be considered in more depth in table 2.2.

Table 2.2: The different schemes used for categorising text and how they are proposed to be used.

Category Scheme	**Description**	**Use**
Subject Matter	"*Identification of what the communication is about*"	When investigating views/ attitudes towards a certain issue, theme or topic. As they enable direct determination of what the text is about, and are specifically derived from the research question.
Directional	"*In the comparative examination of attitudes*"	When comparing different views on the same issue.
Ends and Means	"*The examination of the ends* (the goal or issue) *and the means* (the way or factors) *used to attain, or result in, the ends*"	When considering underlying themes, or factors, which have resulted in, or are the reason for, the issue identified.
Evidence based	"*The evidence presented by a source to support their assertions*"	When investigating views/ attitudes towards a certain issue, theme or topic.

As the main aim was to identify the issues the stakeholders identified in relation to the research question, the subject matter of the response is the best measure of this. Subcategories were also used as they gave great scope to the coding, enabling the depth and context of the response to be utilised; it is because of this, the use of subcategories is advised by many in the field, (de Vaus, 2001; Holsti, 1969; Krippendorff, 1980; Neuendorf, 2002; Weber, 1990), as they increase the validity of the research. It should be noted that with this increase in validity comes the potential decrease in reliability, as the more subcategories used, the greater amounts of coder judgement is required. Thus it is of paramount importance that the categories, and especially subcategories, are well defined, enabling judgements to be methodical and justifiable, and in so improving reliability. Therefore a coding dictionary, which contain clear definitions of all categories and subcategories as well as lists of words/ codes that fit within the category/subcategory, and dichotomous decision trees, was produced (appendix two C).

2.4.2.3 *Initial round of coding and production of the coding dictionary*

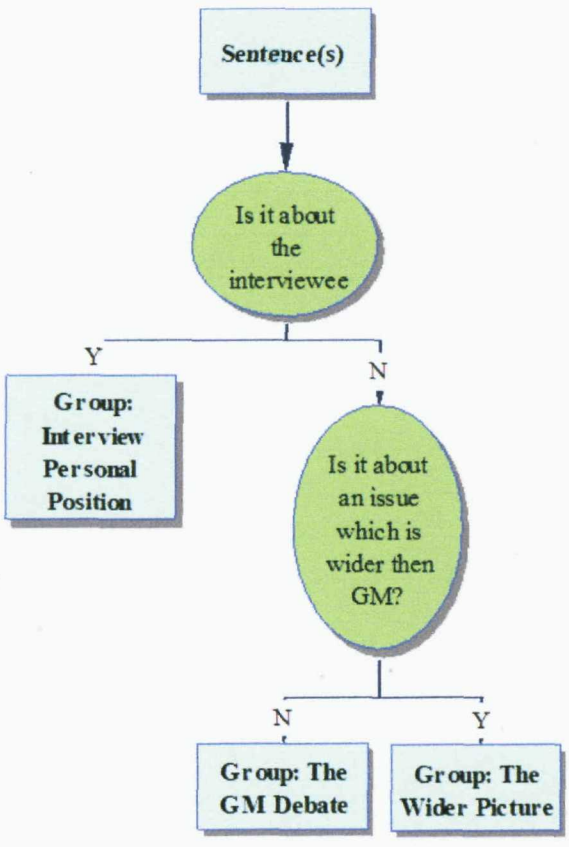
The initial round of coding enabled the production of a coding dictionary (appendix two C). Coding dictionaries are important as they give structure to the coding decision by acting as a guide. There are numerous preformed dictionaries available for the coding of social research, including the well known Harvard Psycho-Sociological dictionaries (Stone et al., 1966) and Lasswell Value Dictionary (LVD) (Lasswell and Namenwirth, 1968). The majority however are aimed at the social sciences: enabling the coding of political, economic, psychological and sociological themes. Custom dictionaries can be made and used by the researcher when those available are inappropriate, however this tends to be rather time consuming. By constructing the dictionary from the message sample (interview data) it improves coding reliability, as a customised dictionary is produced specifically to achieve the research aims. Custom dictionaries contain a list of the themes and sub-themes which are to be used, along with clear definitions, outlining the range of issues which fall within that theme.

The production of the coding dictionary was an iterative process which went hand in hand with the initial coding of the maps. As the maps were initially coded, new themes were identified, these were then added to the coding dictionary. Once all the maps had been coded, then all the themes should have be identified. The coding dictionary was then reviewed. Definitions of themes were tightened up to ensure their clarity and example statements were used to illustrate each theme. Themes which were overlapping or not mutually exclusive were combined; a good example of this was with "transparency" and "openness" which were often used by stakeholders to express the same points in relation to the regulatory process. Thus these were both combined under the heading "transparency" with the definition stating the inclusion of any reference to openness. Finally a series of dichotomous decision trees were produced; these aided the coding process when there were complex coding rules to follow or themes which were hard to define. Dichotomous decision trees are used to aid in judgement formation and therefore reduce bias (Kvale, 1996). They enable single judgements to be made at a time,

and this permits coders to review each decision in a structured way (Neuendorf, 2002). Decision trees were used when coding for categories and subcategories, to aid decision making, an example of which is represented in figure 2.3 (alternatively see appendix two c). By starting with the most broad grouping of themes the user will be redirected through a series of yes/no questions, and subsequently through a series of decision trees until the correct theme is arrived at.

Once the coding dictionary and decision trees had been finalised then the maps were recoded. This was required as the final themes were only identified after all the maps had been initially coded; so some of the themes identified in the latter part of coding might be more appropriate for some of the maps coded first, also some of the initial codes might have been groups into overarching themes so a second round of coding is a mandatory requirement.

Figure 2.3: An example of the dichotomous decisions used as a guide when coding sentences into themes



2.4.2.4 *Testing the reliability and validity of the coding scheme*

As previously mentioned, the validity and reliability of the coding scheme was tested using external coders, (Weber, 1990). The way in which this was done is presented below and, in doing this, it ensures that the categorisation scheme is objective to enable reliable replication of results, and that the coding scheme accurately reflects the research question and therefore it is a valid representation, (Holsti, 1969; Krippendorff, 1980; Neuendorf, 2002; Weber, 1990).

A subset of maps were sent to an external coder, this subset compromised of one map for each of the twelve research questions selected at random across the five stakeholder groups. Using external coders as a measure of semantic validity, "*the extent to which the coding units which are classified together possess similar connotations*" (Weber, 1990) improves the reliability of the method as well as the internal validity of the classification system, i.e. the appropriateness of the categories and codes. Levels of agreement and co-variation between coders exceeding Cohen's Kappa (K) 0.70 are considered to be sufficient as this is a standard often cited in the literature (Holsti, 1969; Krippendorff, 1980; Neuendorf, 2002; Weber, 1990), although there is no firm rule of thumb. The extent of agreement and co-variation between coders was measured; initial coding gave K values of 0.5789, suggesting revision of the coding dictionary was required.

2.4.2.5 *The revision of codes and retesting*

Revision is an important part of the process; often it involves further clarification of codes or categories within the dictionary, but in some cases it can be more severe, entailing the reformulation of categories or even the dropping of some category schemes (Krippendorff, 1980). As part of the revision process, a meeting with the external coder to review the initial coding was arranged. By jointly coding the same twelve maps, it enabled further exploration of the coding dictionary and process. A number of subtle revisions were made, table 2.3; the most significant revision was the inclusion of Issue-Suffix, as a lot of the sub-theme had been coded under different themes (the majority Prefix-Issue) thus these needed to be recoded correctly. Prefixes and Suffixes were used to split

categories like 'Issue' (where the stakeholder identified a specific issue they perceived in relation to the research question) into sub-categories. Prefixes-categories, were subcategories in which the initial theme is related to a specific subject (an individual or a group), for example an issues with scientists (Scientists-Issue); and categories-suffixed, were sub-categories of the initial themes which related to an object or issue, for example an issue with agriculture (Issue-Agriculture). The theme definitions held up well: no rewording was required and neither were any regrouping required for over lapping themes.

Table 2.3: The issues arising from the first round of external coding and the revisions made.

Issue	**Revision**
No theme for comments about crops already commercialised where the interviewee saw their potential effect as being neutral: neither beneficial nor risky.	The inclusion of **AC Neutral** as a sub-theme
No theme for comments that mentioned issues in relation to a specific description/ issue or object what was in the wider context of GM	The inclusion of the theme **Issue-Suffix**; and the sub-themes: **Issue-Agri; Issue-Bigger; Issue-Bureaucracy; Issue-Econ; Issue-Envi; Issue-Fad; Issue-FC; Issue-FMP; Issue-Food Security; Issue-Landuse; Issue-Not; Issue-Scientific; Issue-Social/Envi; Issue-Technology; Issue-Theoretical; Issue-Wider**
No theme for comments that identified a specific wildlife issues associated with GM	The inclusion of **Wildlife-SIssue**
No theme for comments that discussed the regulatory process in relation to how it has been communicated.	The inclusion of **RP-Comm**
No theme for comments that discussed the regulatory process in relation to what should be included.	The inclusion of **RP-Inclusion**

Recoding of the maps, after revising the dictionary, improved the K score to 0.969; however due to the extent of coding revision, another round external validation was required to confirm that the coding revisions made are appropriate. The second round of external validation ensured that the improved K score was not just an artefact of the joint revision but due to the improved coding dictionary and procedure. Due to time constraint of the external coder, the second round of

coding only involved three maps selected at random across the stakeholder groups. The second round coding procedure resulted in a K score of 0.7636, which was much improved from the initial round K score (0.5789), and exceeds the required K score stipulated in the literature (K score >0.70) (Holsti, 1969; Krippendorf, 1980; Neuendorf, 2002; Wengraf, 2001) (section 2.4.2.4).

Something to consider when attempting to attain high levels of both validity and reliability, is that often these each comes at a cost to the other (Neuendorf, 2002). To improve reliability, for instance, coding schemes often have to be simplified. Simplification often means that the coding scheme becomes less representative of the initial research question and then validity of the system is reduced. Therefore, there is a fine line that needs to be sought; which means that constant revision, using multiple coders, is a necessary part of the process

2.4.2.6 Recoding all the text and the final tests for reliability

Once a level of acceptable consistency was reached between researchers and all amendments to the coding dictionary were made, all the interviews were recoded. A final test of the reliability and validity of the coding methodology was made, to test for coder reliability, as much as to test the methodological process. Frequently, coding the main body of text is such a long and arduous process, that it can often result in coder fatigue, as well as creating subtle changes in the coders understanding of the coding rule. Both of these can lead to a loss in the reliability of the coding process and so need to be examined. After the final recode, a random selection of interviews were chosen and recoded once more, these were then compared to the original ones. Also the questions coded in the final round of external coding were also compared. This enabled a measure of temporal reliability to be gauged, K score 0.928 shows that temporal reliability was high.

2.4.3 Statistical analysis

Qualitative coding of the data enabled the vast amounts of raw data produced to be transformed in a way that lent itself to quantitative statistical analysis.

Quantitative analysis of the data allowed key themes to be extracted from the mass of data generated in the qualitative coding. By being able to identify the key concerns of each stakeholder (or stakeholder group) in relation to a specific research question, the primary concerns of the stakeholder groups can be assessed and compared. This way of identifying the key components from background 'noise' is commonly used in quantitative ecology; for example it is being introduced into chemical ecology where key chemicals are identified from a mass of different chemical signals (van Dam and Poppy, 2007).

The quantitative statistical analysis was carried out in two stages: firstly, the key themes raised by each of the stakeholder groups in relation to the research question were identified using a "proportional occurrence" score (section 2.34.3.1); secondly, the stakeholder groups were compared in relation to the themes raised via Principle Component Analysis (PCA) (sections 2.4.3.2).

The findings of the "proportional occurrence" and PCA output have been used in combination when discussing the stakeholders concerns in relation to the environmental effects, regulatory approach and potential management goals and assessment endpoints as there are numerous overlaps. It should however be noted that "proportional occurrence" was used to identify the key themes identified by the stakeholder groups. While the PCA illustrated the differences between stakeholder groups in terms of their responses. Both could be used when considering similarities between the groups. In the general discussion (Chapter Six) the findings of the two methodological approaches are separated into two succinct tables (table 6.1 and 6.2) which summarises the findings of each approach.

2.4.3.1 *Stage one: the identification of themes raised by the individual stakeholder groups*

Determining the main issues each stakeholder group identified, in response to the individual research question, is central to the research aims. The issues are identified through the coding of the stakeholders' responses into themes. The stakeholder groups' response can then be analysed in terms of: the proportion of the response given over to each of the themes and the themes identified by the greatest amount of respondents within each group. This classifies the themes in terms of their relative importance, based on the assumptions that: themes present in numerous responses with in a group are going to be more relevant to that group's opinion than themes which are only present in the response of one individual; and that themes which take up a greater proportion of the stakeholders' responses are going to be more important then those which take only a smaller proportion. It should however be noted that the time an interviewee spent on a theme might not, in some cases, truly reflect its importance since some interviewees might spend a few sentences on a key theme which they deem to be an obvious issue and as such not worthy of an in depth discussion; yet spend large proportions of time on a more obscure point that needs a more in depth explanation but might not be as important a point. This is a limitation of this methodological approach and a great deal of time has been spent considering other approaches which could be taken. It has however been decided that all methodological approaches which could be used to identify the key themes from the lists drawn out by the stakeholders have their own inherent problems and weaknesses; therefore the proportion of time taken by a stakeholder on a theme will be used as a measure of importanc.As it was deemed to have the least amount of inherent problems and weaknesses associated with it. However it will not be used as the sole measure, instead it will be used in combination with the number of stakeholders who mention the theme. By using the two measures in combination, it will minimise the impact the inherent methodological weakness have on the results as a whole.The key themes for each stakeholder group were identified on the basis of a function of both number of respondents mentioning it (M) multiplied by the proportion of time spent discussing the theme (P). Thus key themes were selected on the basis of their M x P Score, which from this point forward will be referred to as "proportional occurrence". A proportional

occurrence score of 0.2 could be generated, either: by a theme that represented 20% of the stakeholder group's response but was only identified by one stakeholder representative; or by a theme which took up a much smaller proportion of the group's response, say 5%, but was identified by four of the stakeholder representatives. "Proportional occurrence" scores >0.10 were identified as key themes for each stakeholder group. While it is acknowledged that a "proportional occurrence" of 0.10 is an arbitrary number and indeed any could have been chosen as a cut off point, 0.10 was selected as a threshold based-line on the principle that, if a theme represents <10% of the total response then to be considered a key theme it needs to be mentioned by at least two or more representatives.

2.4.3.2 *Stage two: identification of differences between stakeholder groups in terms of the themes identified*

Principle component analysis (PCA) was used to measure the variation in themes between stakeholder group responses, and is one of the suggested ways of analysing concept maps (Eden and Ackermann, 1998). PCA was performed using the Multi-Variant Statistical Package (MVSP) Version 3.1 (provided by Kovach Computing Services) on the "proportional occurrence" data. PCA is an ordination method which enables a co-variation (correlation) matrix to be produce, from which axes that represent the variation within the dataset can be identified. The variables (themes) and indeed the cases (stakeholder groups) can be scored in relation to the axis and positioned relatively within a PCA matrix or Euclidean biplot. Distinctions between the groups and themes can then be made based on their positioning; those which cluster together are likely to be associated with one another. Therefore themes which cluster with a certain stakeholder group represent the key views/concerns of that group; likewise stakeholder groups which cluster together are likely to share similar concerns. The opposite is true for stakeholder groups and themes which load in opposite directions on the axes; in these cases it either identified stark differences between the stakeholder groups in their responses or themes which do not feature in the responses of particular groups. PCA relies upon statistical independence of the two axes. That is to say,

variables (in this case, themes) which contribute strongly to explaining the variation on one axis are not involved in explaining the variation on the second. This statistical independence is met in this study for PCA to be used. There is a question however, as to the real independence of the variables (themes) because they arise from the same cohort of farmers and as such two themes mentioned by the same farmer are not independent from one another. This however would be the case of any PCA which used multiple measures from the same individuals whether it be shell measurements, behavioural responses or surveyed responses. Obviously for the sake of true objectivity, real independence would be the gold standard. Because, going back to the survey responses, if it can be shown that there is real independence as well as statistical independence between the PCA axes then it can be assumed that the two explanations of variation given on axis one and two provide distinct explanations of the differences stakeholder groups attitude. If however there is only statistical independence rather than real independence, then the explanation of variation becomes less distinct with the two explanations being interrelated (however, it should be stressed not at the statistical level). It is however not overly apparent the effect that this might have on this study. Testing whether so called 'real independence' has been achieved is a hard measure to ascertain, and as such, for this study statistic independence is sought.

Chapter Three

The stakeholders' environmental concerns relating to the deliberate release of GM crops

3 Chapter Three: The Stakeholders' environmental concerns

3.1 Introduction

The use of GM crops in agricultural production could potentially cause environmental harm, although the extent, scope and consequences are debated (AEBC, 2001; Conner et al., 2003; Dale et al., 2002; Uzogara, 2000b). Classically, the immediate and delayed environmental risks as well as those that are both direct and indirect are considered when applying for deliberate release of a GM variety (Council of the European Commission, 2001b). These are often discussed in terms of a series of hazards like gene flow, effects on non-target organisms and the potential to alter farm management practices. The risks are then evaluated in terms of the potential of exposure to these various hazards (Council of the European Commission, 2001b).

The environmental implications of deliberately releasing GM crops are perceived differently by those involved in the debate (Poortinga and Pidgeon, 2004). This is driven by a number of factors, discussed in some detail in introduction section X. The stakeholders' perceptions of the potential environmental implications will affect the way they feel towards both the deliberate release of GM crops and the regulatory process ensuring environmental protection. Indeed the scope of the regulatory process has been questioned by a number of the stakeholders within the debate (NRC, 2002). Central to this, has been a difference in stakeholders' perceptions of what constitutes an environmental risk and the feeling that the narrowness of the regulatory scope means that some environmental risks are not evaluated.

This study aims to explore this by investigating the environmental concerns different stakeholder groups hold, through use of semi-structured qualitative interviews. By gauging various stakeholder environmental concerns, evaluation problematic issues can be made. Comparisons of stakeholder groups were also

made in terms of the similarities and differences in their perceptions of the risks posed.

Identifying the similarities between the stakeholders' responses can then be focused upon, as they represent areas of mutual concern. Being able to recognize areas of concern that are shared can enable a platform to be built potentially giving some cohesion to the debate. This platform can then be used as a starting point of the regulatory process and will enable the exploration of other areas of the environmental risk debate. Also, by drawing comparisons between groups, the groups' difference in perception of environmental risks can also be identified, and then ways to address these can be sought. Addressing the different perceptions of environmental risks, whether this be their inclusion in the regulatory process, or clear explanations as to why they are not officially or scientifically considered as risks, will also reduce the polarisation within the debate that is thwarting any form of progress in Europe, whether that be GM adoption or rejection.

The three main aims of this chapter are:

1. To identify the environmental risks each stakeholder group perceives in relation to the deliberate release of GM crops
2. To compare stakeholder groups' perception of the environmental risks to uncover the similarities in their concerns. These can then be used as a starting point of the discussion on environmental risks, by improving stakeholder cohesion. They also are key themes which need to be incorporated in the regulatory process.
3. To compare stakeholder groups' perceptions of risks to highlight the differences in their concerns; these can then be used to explain some of the polarisation already experienced within the debate.

3.2 Methodology

The methodological approach has been set out in Chapter Two, (sections 2.2.4-2.4.3). This chapter investigated the stakeholders group's responses to research questions:

RA1a:"*Do you have any environmental concerns over the deliberate release of GM crops?*" (General concerns)

RA1ba: *Among the scientific concerns which have been raised, include issues of gene flow, what are your feelings about the potential risks gene flow might pose?*" (Gene flow)

RA1bc: "*Among the scientific concerns which have been raised, include issues of non-target organisms, what are your feelings about the potential risks posed to non-target organisms?*" (Non-target effects)

RA1bd: "*Among the scientific concerns which have been raised, include issues of potentially altering farm management practices, what are your feelings about the potential risks alterations to farm management practices might pose?*" (Alterations to farm management practices).

3.3 Results

The results section will be split into four parts corresponding to each of the interview questions. Each part starts initially with the identification of the key themes for each individual stakeholder group, using the "proportional occurrence" method (Chapter Two, section 2.4.3.1), and then goes on to draw comparisons between stakeholder groups in terms of the similarities and differences between groups' responses, using principle component analysis (PCA) (Chapter Two, section 2.4.3.2).

3.3.1 RA1a"Do you have any environmental concerns over the deliberate release of GM crops?" (General concerns)

Table 3.1: Summary of the key themes each identified for each stakeholder group's response to RA1a (General concerns). CCP= comparisons with current conventional practices; RP=regulatory process; C-b-C=case-by-case; GF=gene flow; HT=herbicide tolerance; AC=already commercialised; FC=future crops; II=intensification and industrialisation of agriculture.

	Farmer	**Government**	**Industry**	**NGO**	**Scientists**
Key themes and "proportional occurrence" scores	CCP 2.226	GF SIssue 1.19	HT SIssue 0.238	GF SIssue 0.622	C-b-C 0.515
	RP Needed 0.204	CCP 0.69	AC No Concerns 0.16	Uncertainty 0.171	FC 0.314
	C-b-C 0.152	RP Needed 0.326	FC 0.13	II 0.114	CCP 0.291
	Concerns No 0.145				AC No Concerns 0.211
					Agri Issue 0.114

The farmer stakeholder group overwhelmingly identified the need to compare GM crops to current conventional practice (CCP) when discussing the environmental concerns (table 3.1), stating that they perceived the environmental risks posed by GM would be no worse then those resulting from conventional practices (appendix 3A, table 1.1). While they stipulated they had no environmental concerns in relation to GM crops, they did identify the need for the regulatory process to govern GM release, stressing the point that, for crops which had gone through a regulatory procedure, they had no environmental concerns "*providing the crop has been thoroughly tested, researched*" (FC) (appendix 3A, table 1.1). The group also discussed the need to consider GMs on a case-by-case basis "*as*

the impacts are likely to be mixed" (FE) (appendix 3A, table 1.1) and each crop needed to be evaluated in respect to its own risks and merits.

The government group also drew comparison with current conventional practice as "*there is the possibility to introduce genes through conventional methods which are a risk from an environmental point of view, for instance HT.*" (GA) (appendix 3A, table 1.2); although they did identify gene flow as being a specific issue in relation to GM crops "*there is the question of the transfer of genes from the* [GM] *plant itself to wild relatives, which would have an impact on the ecosystem the relatives were growing in"* (GB) (appendix 3A, table 1.2). They too identified the need for a regulatory process governing the deliberate release of GM crops "*but it is very important to regulate it. The potential for it to do harm is out there.*" (GD) (appendix 3A, table 1.2).

The industry group made a clear distinction between those crops already commercialised and the potential future crops when discussing their environmental concerns. Stating that with crops already commercialised they had no concerns, as "*they have been given approval to be released into the environment; you have to assess all the risks. So of the crops which are released I don't think there haven't been any substantiated claims associated with them.*" (IB) (appendix 3A, table 1.3); but for future crops this could be different "*because obviously with new traits we will identify different hazards as the ones we have described"* (ID). They also specifically identified herbicide tolerance as an issue which is discussed too much in relation to environmental risks, "*because we can get novel herbicide tolerance from other means... ...a lot of the discussion around herbicide tolerance is a discussion about herbicide management.*" (ID) (appendix 3A, table 1.3).

The NGO group, like government, singled out gene flow as a specific environmental concern of GM crops, "*there is the obvious risk of mutation or out crossing into related species"* (NE) (appendix 3A, table 1.4); which not only had

environmental implications but also agricultural ramifications "*Whether there will be gene flow into wild related plants; whether you are going to have gene flow into either neighbouring crops having effects on neighbouring farmers' abilities to farm.*" (NC) (appendix 3A, table 1.4). They also discussed their environmental concerns in relation to much broader issues: uncertainty in the form of unknown or unforeseen risks was one of the concerns which came up ("*There are many, many concerns, that I mean a lot of them are unforeseen*" (NE) "*...there are unaccepted levels of risks, unknowns associated with release*" (NF) (appendix 3A, table 1.4)); as well as the potential of GM to further intensify and industrialise agriculture "*we've deep concerns about how it will further intensify agriculture*" (NC) (appendix 3A, table 1.4).

The scientists group, like industry, distinguished between those crops already commercialised "*products which have gone through the regulatory system I have no concerns with*" (SF) and potential future crops "*we don't know what will be coming on the market in the future I think it is good that risk assessment is made and that risks are evaluated.*" (SG) (appendix 3A, table 1.5). Again, like the industry group, scientists made the regulatory process the basis for this distinction. The need to consider GM crops on a case-by-case basis was also identified by the group who felt, "*you need to consider the particular crop trait and how it will be used. The environmental risks they pose are case-by-case really.*" (SA) (appendix 3A, table 1.5). They also drew comparisons with current conventional practices stating that the environmental concerns they held were more an issue of agriculture in general, then of GM "*compare glyphosate tolerant grasses produced though both GM and non-GM methods. Both raise comparable issues in terms of a risk assessment you cannot separate them, there is really no fundamental difference.*" (SH), "*they are around changes in the nature of agriculture which certainly have environmental impacts that are not strictly driven by GM crops*" (SD) (appendix 3A, table 1.5).

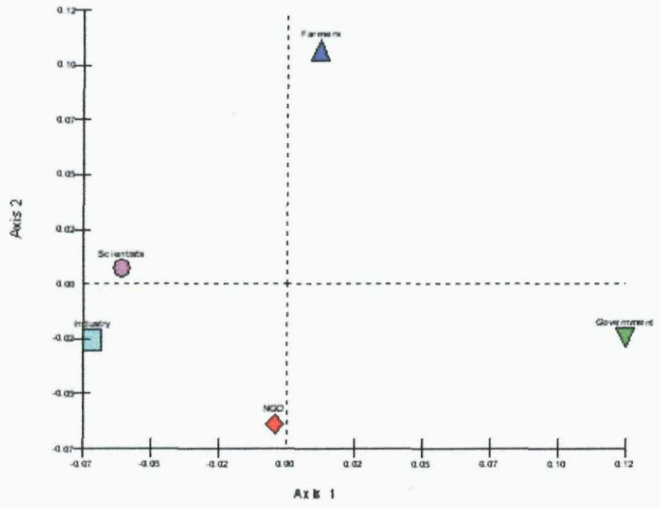
3.3.1.1 Stakeholder group comparisons of themes

There are clearly some themes that transverse stakeholder groups (table 3.1). The farmer, government and scientists groups drew comparison in terms of the environmental concerns associated with GM crops to those currently posed by conventional practices. Only the government and NGO groups identified gene flow as being a specific environmental concern; while the scientists and industry groups made distinctions between those crops already commercialised and potential future crops. The farmer and scientist groups stipulated the need to consider GM crops on a case-by-case basis; yet only the farmer and government groups directly stated the need for the regulatory process in relation to the environmental concerns. However the distinctions made by the industry and scientists groups between future crops and those already commercialised implies that they too perceive the regulatory process as being a necessity.

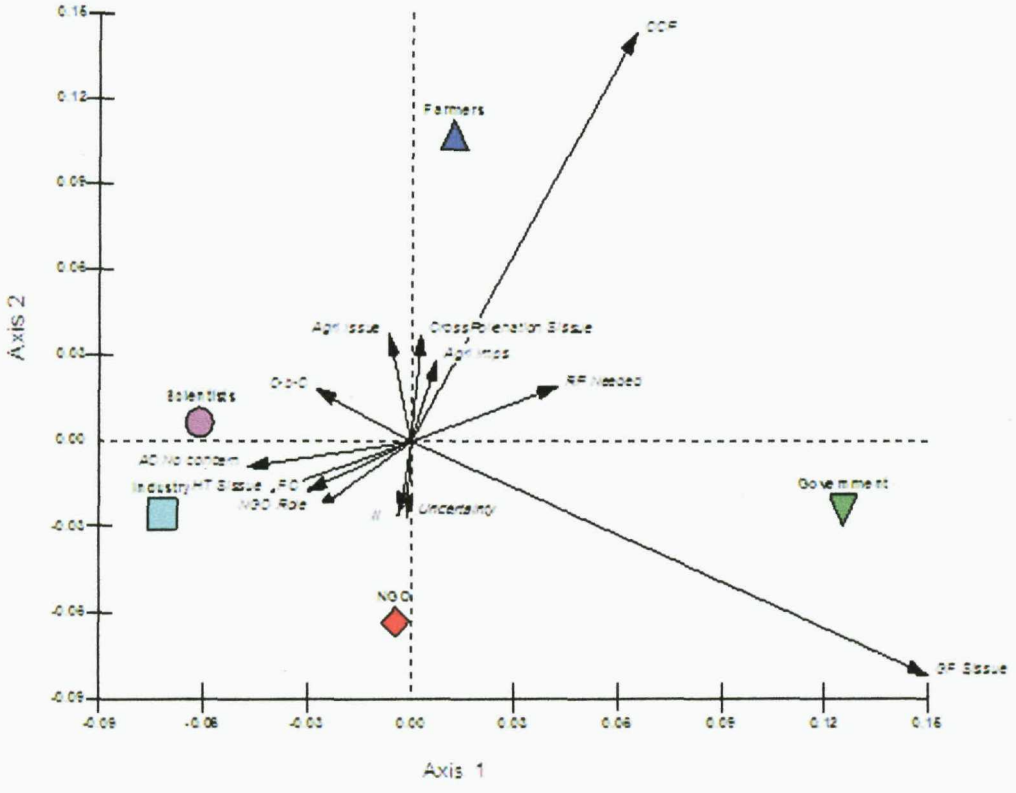
Using PCA, 73.53% of the variation between the five stakeholder group's responses was explained by the two primary axes (figure 3.1A). Fourteen themes from the initial list of one hundred identified in the stakeholders' responses loaded either negatively or positively on to either of the two axes (appendix 3B Table 1). In relation to axis one, the responses of the government stakeholder group seems to be diametrically opposed to that of the industry and scientists groups; where as on axis two, the responses of the NGO group and the farmer group also seem to be completely opposed.

Figure 3.1: A) Stakeholder group positioning on the two PCA axes accounting for 73.53% of the variance in the responses to interview question RA1a general concerns. B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes. Farmer= blue triangle; government= green inverted triangle; industry= blue square; NGO= red diamond; scientists= pink circle.

A)



B)



The government group identify with themes such as gene flow being a specific issue and the need for the regulatory process and GM testing (see section 3.1.1); whereas the industry and scientist groups cluster with themes drawing clear distinction between those crops already commercialised, perceived to be of no environmental concern, and potential future crops (figure 3.1B).

A number of themes separated the industry and scientists groups, explaining the groups' variation in relation to axis two. The scientists group stated the need for a case-by-case evaluation; seeing a number of the environmental risks as an agricultural issues (see section 3.1.1); whereas the industry group discussed the specific issues surrounding HT crops.

The farmer group associated with themes conveying the need to draw comparisons to conventional practice; whereas the NGO group identified with gene flow being a specific environmental concern relation to GM crops as well as the issues of uncertainty and GM crops potential to intensify and industrialise agriculture (see section 3.1.1). The diametrically opposed positioning of both the farmer and NGO groups is indicative of highly divergent views. Thus the farmer group are unlikely to identify with uncertainties surrounding GM crops or the potential for them to industrialise agriculture. In the same way as the NGO group are unlikely to see GM crops and the environmental risks they poses as comparable to conventional practices.

3.3.2 RA1ba: "Among the scientific concerns which have been raised includes the issue of gene flow, what are your feelings about the potential risks gene flow might pose?" (Gene flow)

Table 3.2: Summary of the key themes each identified for each stakeholder group's response to RA1ba (Gene flow). CCP= comparisons to current conventional practices; L of K= lack of knowledge; Agri=agricultural; GF= gene flow; C-b-C=case-by-case; M&M= management and monitoring; RP= regulatory process; Comp= comparisons; SIssue=specific issue; FC=future crops.

	Farmer	Government	Industry	NGO	Scientists
Key themes and "proportional occurrence" scores	CCP 0.909	GF SIssue 0.932	Public Understanding 0.233	Comp Canada 0.153	C-b-C 0.331
	L of K 0.277	CCP 0.159	GF SIssue 0.222	Benefits 0.126	CCP 0.333
	Agri Issue 0.246	C-b-C 0.157	RP Needed 0.166		Weediness SIssue 0.111
		M&M 0.117			FC 0.106
		Context Agri 0.111			

The farmers group identified the need to compare GM crops to current conventional practice when discussing the environmental concerns relating to gene flow "*It has been well known in agriculture since agriculture first began*" (FH) "*I don't think there is strong evidence to show that would happen anymore than it does from conventionally bred varieties.*" (FJ) (appendix 3A, table 2.1). Indeed they gave examples from conventional agriculture where they have had to manage and restrict gene flow "*...for many years we have been growing high eurcimide rape varieties which are rape varieties with high levels of euric acid in them. Now you have to be careful with this sort of stuff as if you feed it to humans they show lesions on their livers... ...we have always managed to grow these crops side-by-side without causing any liver failure.*" (FG) (appendix 3A, table 2.1). They saw gene flow as an agricultural issue rather then a GM specific issue, "*I would say it is more of a farming issue...* again giving examples from

conventional practice ... *we once grew fodder rape on a seed contract. We had to have a thirty metre strip from any other oilseed rape crops or any other related species."* (FB) (appendix 3A, table 2.1). They did however caveat their response by identifying their own lack of knowledge "*I suppose that I am not qualified to answer whether there is a huge risk*" (FD) (appendix 3A, table 2.1).

The government group identified gene flow as being a specific issue of GM, "*I think that is the biggest worry, gene flow into the flora which it wasn't intended to get into...*" (GC), "*It may become an issue when gene flow results in the movement of characteristics: Pesticide resistance; herbicide resistance. It may become an advantage to the environment."* (GD). The group also identified the need for it to be considered within the context of agriculture, "*So I think that gene flow is an important issue it is something that we need to look at. But it has never been looked at in the context of conventional breeding"* (GA) (appendix 3A, table 2.2); making references to current conventional practices, "*...yes gene flow has the potential to transfer genes into the wild population. But that is equally the case for conventionally bred crops... "* (GA) (appendix 3A, table 2.2). In relation to the risk of gene flow they identified that GM crops need to be considered on a case-by-case basis "*with gene flow it depends what the gene is so I think one of the problems in all of this is that people are talking about GM s as if they were all one thing"* (GB) (appendix 3A, table 2.2) and in relation to potential management and monitoring strategies. Identifying the need to monitor "*that this* [monitoring] *is a research area so should be part of the research*" (GF) (appendix 3A, table 2.2); but that management strategies, in the UK at least, would never be considered as a prevention method for gene flow "*Isolation, certainly physical isolation, for prevention of gene flow will never be, certainly the ACRE panel I was on. Would never be used as a mechanism for restricting the spread of the genes from GM crops"* (GD) (appendix 3A, table 2.2).

The industry group also identified gene flow is a specific issue in relation to GM crops "*It needs to be carefully considered. I think it is carefully considered."* (IB); and that the regulatory process is needed "*The risks of cross pollinating are part*

of the scientific regulation process. From a scientific point of view harm that maybe cased by them to human health and the environment then this is absolutely needed." (IC) (appendix 3A, table 2.3). They also identified the public's understanding of gene flow as being a key issue and that there seems to be a fundamental lack in the public's knowledge in relation to gene flow, GM and science in general (appendix 3A, table 2.3), something not mentioned by any of the other groups.

The NGO group drew comparisons with Canada in relation to the experiences they have had with the gene flow of herbicide tolerant transgenes and discussed the impact that this has had on the environment as well as farming *"...conventional as well as organic farmers who have been massively affected in areas of Canada where GM crops have been grown for some time"* (NE) (appendix 3A, table 2.4). The other theme identified by the group was the benefits, which were discussed in relation to there being none or very few which have materialised. They therefore questioned the need for GM crops, especially when considering them in the context of the risks posed by gene flow, *"It is not as if the case has been shown that we need agricultural biotechnology."* (ND); "e*specially as I am not convinced there are any economical benefits anyway"* (NG).

The scientists group made comparisons with conventional practices, as they felt conventional crops are often bred to have the same characteristics as the varieties of GM currently available so the risks posed are similar (*"Many of the issues are also issues for conventional crops with the same characteristics."* (SH) appendix 3A, table 2.5). They identified weediness as a specific issue in relation to future GM crops and the potential new traits which might be incorporated as *"they might allow expansion of the range of a crop outside where it can currently be grown because you have an increased environmental tolerance"* (SC) (appendix 3A, table 2.5). They, like the government group, identified that the crops need to be considered in a case-by-case fashion, *"there is a trait issue as well as a crop issue, so crops like oilseed rape they need a lot more close attention than something like*

maize... " (SA) (appendix 3A, table 2.5), singling out future GM crops as a particular issue.

3.3.2.1 Stakeholder groups comparisons of themes

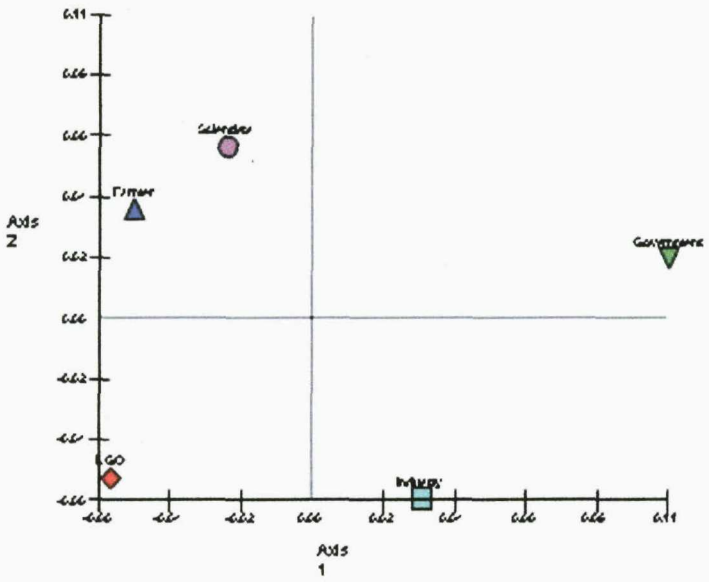
There were again several themes which ran across the stakeholder groups (table 3.2) The farmer, government and scientists groups all made comparisons with conventional practices and both the scientist and government groups also felt that GM crops should be considered on a case-by-case basis. The government group and the industry group discussed the issues associated with gene flow in relation to GM specifically. The NGO group, however, did not identify any of the same concerns (key themes) as the other stakeholder groups.

Using PCA, 61.00% of the variation between the five stakeholder group's responses was explained by the two primary axes (figure 3.2A). Thirty themes from the initial list of eighty eight identified in the stakeholders' responses loaded either negatively or positively on to either of the two primary axes (appendix 3B, Table 2). When distinguishing between the groups in relation to their responses regarding the environmental concerns relating to gene flow four different clusters of stakeholder groups and response can be identified in figure 3.2B.

The farmer and scientists groups gave very similar responses; albeit the scientists group also identified the potential for GM crops to result in weediness issue as a result of gene flow that would have environmental implications (appendix 3A, table 2.5). The two groups stated the need to compare the risks posed by GM crops to those posed through conventional agricultural practices; seeing gene flow very much as an agricultural issue rather than one specific to GM (appendix 3A, table 2.1, 3A.2.5 and 3A.6.4). They based their concerns in relation to gene flow on the traits and characteristics of the crops rather then the production process. As a result of this trait-based approach the two groups saw "*many issues for GM are also issues for conventional crops with the same characteristics.* " (SH) (appendix 3A, table 2.5).

Figure 3.2: A) Stakeholder group positioning on the two PCA axes accounting for 61.00% of the variance in the responses to interview question RA1ba gene flow. B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes. Farmer= blue triangle; government= green inverted triangle; industry= blue square; NGO= red diamond; scientists= pink circle.

A)



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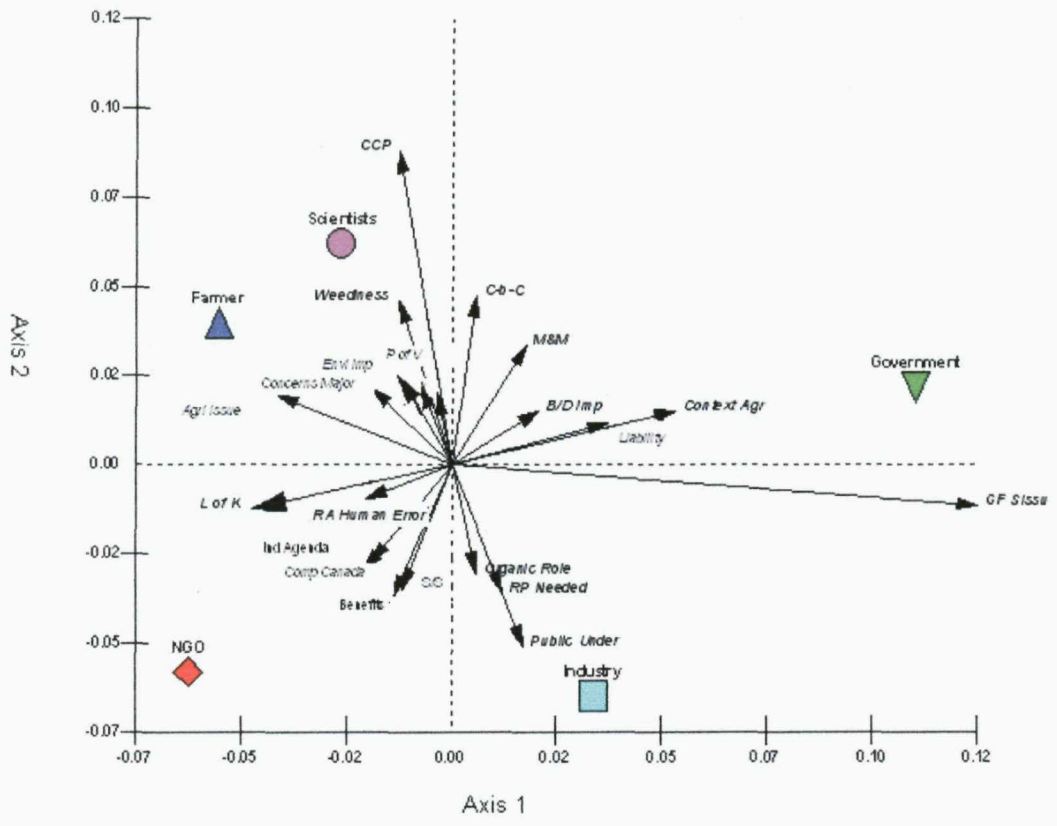


The government group shared the concerns of the farmers and scientists groups in terms of the need to draw comparisons with conventional practices and to take a case-by-case approach. However, the issues which distinguished the government response from the farmer and scientists groups were: the issue of liability in relation to GM gene flow, "*the most important thing is that it will be done and find out who has to pay and so on. From a pollute and pay principle it should be the companies of course*" (GF); the need to consider gene flow within the context of agriculture in general; and in particular the proportion of time the group spent discussing the issues associated with gene flow (appendix 3A, table 2.2).

The NGO group scored negatively on both axes along with a number of themes including the benefits of GM crops which they question "*It is not as if the case has been made to show that we need agricultural biotechnology*" (ND). The group also discussed industries agenda "*But in the context of vested interest... I mean it is fantastic isn't it, I mean if you're aim is to make money...* " (NE) and the implications this might have on the farmer. They drew comparisons with gene flow issues in Canada and the need to consider the relationship between science and society (appendix 3A, table 2.4 & 3A.5.3).

Finally the industry group, they like the government group, identified gene flow as a specific issue; one that required the regulatory process to assess the environmental risks, "*From a scientific point of view harm that maybe caused by them to human heath the environment then this absolutely needs to be assessed*" (IC). A couple of themes are however specific to the industry groups response: the issues of the public's understanding of gene flow and science in general (appendix 3A, table 2.3); and the role the organic sector has had in relation to their pragmatic stance take in relation to GM contamination as opposed to pesticides.

3.3.3 RA1bc: "Among scientific concerns which have been raised, include issues of non-target organisms, what are your feelings about the potential risks posed to non-target organisms?" (Non-target effect)

Table 3.3: Summary of the key themes each identified for each stakeholder groups' response to RA1bc (non-target effect). CCP=comparisons with current conventional practices; P of V= point of view; SIssue= Specific Issue; C-b-C=case-by-case; RP=regulatory process; Agri=Agricultural; C-b-C=case-by-case.

	Farmer	Government	Industry	NGO	Scientists
Key themes and "proportional occurrence" scores	CCP 1.105	GM Trialling 0.513	CCP 0.448	RP Too Narrow 0.20	CCP 1.17
	FSE 0.678	NTO SIssue 0.305	C-b-C 0.125	Agri Issue 0.152	Benefits 0.13
	Benefits 0.157	C-b-C 0.288		FSE 0.12	
	P of V 0.123	IR SIssue 0.244		C-b-C 0.10	
	Concerns General 0.111	CCP 0.120			

Again the farmer group identified the need to compare GM crops with current conventional practices when considering the risks to non-target organisms, with most of the farmer group identifying the benefits of GM when comparing it to conventional practices (FA, FC and FG appendix 3A, table 3.1). They also referred to the FSE and their surprise over the results, *"I though it would be completely the opposite as I saw the big benefit with the GM."* (FC) (appendix 3A, table 3.1). The group brought up the potential benefits of the crops referring to their potential to reduce pesticides: *"there are lots of reports of reduced pesticides use from all other countries"* (FA) (appendix 3A, table 3.1) although they did also state they had general concerns about GM in relation to non-target effects. They added a caveat to a number of their answers by stating this was only their point of view.

The government group also mentioned GM trialling, although did not discuss the FSE specifically, stating the need for trialling "*any regulators will be expecting to see the results of field trials*" (GB). They saw the effects GM crops have on non-target organisms as a specific issue "*particularly I guess insect varieties here where plants are designed to resist the pest*" (GB); "*There is an issue of when you have insecticide in the plants*" (GF) identifying insect resistant crops in particular as an issue. They did however specify the need to look at GM crops on a case-by-case basis (GB, GD and GG appendix 3A, table 3.2) and made comparison to current conventional practices. They argued that insect resistance has been conventionally bred into crops, just with different sorts of insect resistance, arguing that this is a reason to look at the trait rather then the modification method when evaluating the crop "*Again this does beg the question that it is the trait you should be looking at, not the way you got there*" (GA).

The industry group, like both the farmer and government groups, identified the need to draw comparisons with current conventional practices; stressing that in some cases they could be beneficial by reducing the chemical usage (IA appendix 3A, table 3.3) and in other cases they see conventionally bred crops posing similar environmental risks (IB appendix 3A, table 3.3). The industry group also, like government, discussed the need to consider GM crops on a case-by-case basis as "*it is very easy to see why an insect resistant plant which has a toxic element to some insects could have an impact... ...you always have to look at the individual case and example*" (IE).

The NGO group saw the regulatory process as being too narrow when it comes to non-target organisms "*Yes there is that overlying assumption, a tendency not to look at it or to discount this as important*" NC (appendix 3A, table 3.4). They identified that the risks to non-target organisms was an agricultural issue rather then a GM specific one, linking the environmental risks with the intensification of agriculture post-war (ND and NG appendix 3A table 3.4) and discussed the need

to consider GM crops on a case-by-case basis: ("*the answer on that case depends on what you are talking about. If it is going to affect pests then it is going to effect non-pests the question is this will differ from crop to crop place to place.*" (NA) (appendix 3A, table 3.4)). Like the farmer group, the NGO group made reference to the FSE, however they used the FSE results to support their point that GM crops have non-target effects "*the FSE showed that with several of those crops you end up with fewer other plants growing in the field.*" (NB) (appendix 3A, table 3.4).

The scientists group, like the farmer group, identified the need to make comparisons with current conventional practices, elaborating on the risks to non-targets posed by conventional agriculture and the need to consider GM within this context (SA, SC, SG and SH appendix 3A table 3.5). They also brought up the issue of the potential benefits which could result from GM crops ("*in most cases they are significantly superior to the technologies they are replacing*" SD); fearing that these benefits might be lost due to the hurdles faced by the technology in Europe ("*What worries me is that hurdles are put in place for GM... ...there must be a benefit; farmers are not stupid*" (SC) (appendix 3A, table 3.5)).

3.3.3.1 Stakeholder groups' comparisons of themes

There are clearly some themes which traversed the stakeholder groups (table 3.3). The farmer, government industry and scientists groups all make comparisons to current conventional practices; and indeed for the farmer, industry and scientists group this was overwhelmingly the key issue, with far greater "proportional occurrence" scores then any of the other themes identified by these groups (table 3.3). The need for a case-by-case appraisal of GM crops was identified by the government, industry and NGO groups; the farmer and NGO groups made specific references to the FSE, whereas the government group mentioned GM trialling more specifically. Finally both the farmer and scientists groups mentioned the need to consider the benefits GM crops could deliver in relation to non-target organisms.

Using PCA, the two primary axes accounted for 69.75% of the variation between the groups (figure 3.3A). Nineteen themes, from the initial list of fifty eight identified in the stakeholders responses, loaded either negatively or positively on to either of the two axes (appendix 3B, Table 3). These represented the themes which help explain the two axes and thus around 70% of the variance between responses of the five stakeholder group. All the groups bar the NGO group scored positively in relation to axis one; in relation to axis two, the government group stood out from the rest, scoring negatively (Figure 3.3A).

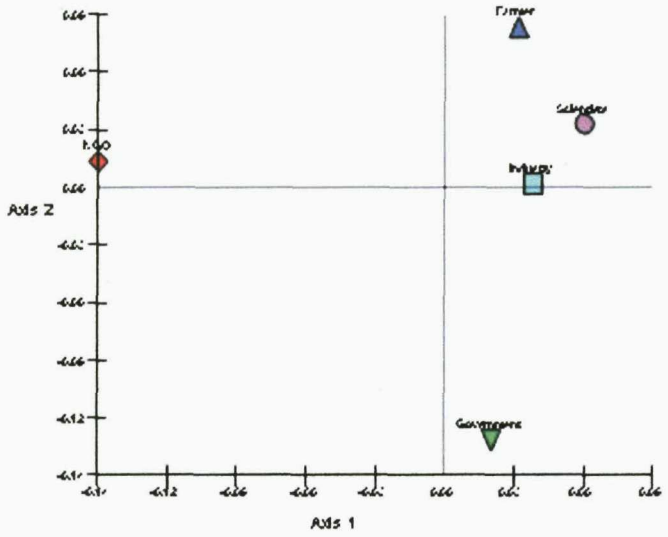
A number of themes clustered in the same direction as the government group (figure 3.3B). The need for GM trialling in relation to non-targets effect; the fact non-target organisms were a specific issue in relation to GM crops, and that insect resistance crops were identified in particular (see section 3.2.3)

Three groups cluster together, scoring positively on both axes: farmer, industry and scientists groups; with a number of themes clustering in the same direction. The need to compare GM, in relation to its non-target effects, with current conventional practices is identified by all three, as is the benefits of GM crops; and both been discussed in detail above. A number of other themes distinguish between the farmer group. The farmer group discussed that while they do have general concerns (appendix 3A, table 3.1) the scientific evidence that GM does have non-target effects is minimal (appendix 3A, table 6.1).

Four themes component load on to the two axes in the same way as the NGO group. The opinion that the regulatory process is too narrow when it comes to examining the non-target effects, that these effects are considered to be an agricultural issue. The group also identified the need to draw comparisons with previous scientific/innovation based issues such as nuclear power (appendix 3A, table 6.3); and the issue of tolerability in terms of the difference between what farmers deem acceptable practice is, and their actually opinion is (appendix 3A, table 6.3).

Figure 3.3: A) Stakeholder group positioning on the two PCA axes accounting for 69.75% of the variance in the responses to interview question RA1bc non-target effects. B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes. Farmer= blue triangle; government= green inverted triangle; industry= blue square; NGO= red diamond; scientists= pink circle.

A)



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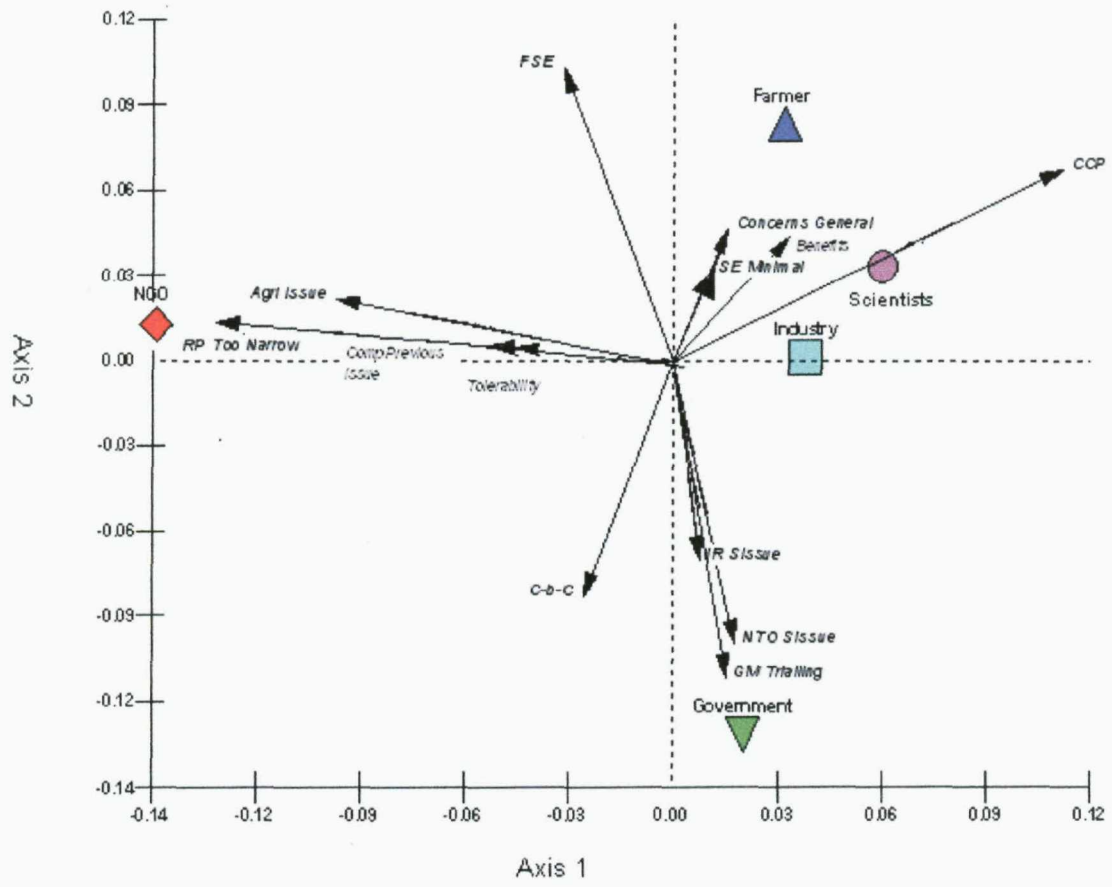


RA1bd: "Among the scientific concerns which have been raised, includes the issue of potentially altering farm management practices. What are your feelings about the potential risks alterations to farm management practices might pose?" (Farm management practices).

Table 3.4: Summary of the key themes each identified for each stakeholder groups' response to RA1bd (Farm management practices). Agri=agricultural; B/D Imp= biodiversity implications; SIssue=specific issue; CCP= comparisons with current conventional practices; L of K=lack of knowledge; II=intensification/industrialisation of agriculture; FMP Imp=farm management practices implications.

	Farmer	**Government**	**Industry**	**NGO**	**Scientists**
Key themes and "proportional occurrence" scores	Benefits 1.859	Agri Issue 0.267	CCP 0.4524	L of K 0.333	Agri Issue 0.948
	FSE 0.23	FSE 0.2128	Benefit 0.25	B/D Imp 0.243	Context Agri 0.28
		Benefits 0.2	Agri Issue 0.163	CCP 0.233	FMP Imp 0.248
		B/D Imp 0.15		II 0.1	Benefits 0.238
		Future Agri 0.108			FSE 0.153
		H/M SIssue 0.10			

The farmers group, when discussing the implications GM crops might have on farm management practices, overwhelmingly identified the potential benefits of GM crops (FA, FC, FE, FG and FJ appendix 3A, table 4.1), discussing their potential to improve flexibility and ease of farming as well as reducing reliance on chemical inputs giving financial as well as environmental benefits. They also made reference to the FSE; questioning the results of the trials "*I know in most instances the results required as part of the FSE would not necessarily be observed*" (FI) (appendix 3A, table 4.1); but stated the importance of running trials over three years "*One of the things which DEFRA is good at is that they did the trials over three years. I think they needed to be understood and studied*" (FF) (appendix 3A, table 4.1).

The government group also made reference to the benefits "*Well all the evidence which I have so far seen is that the potential changes in farm management practices would be beneficial. Reducing cost. Reducing soil erosion. Reducing the number of times chemicals have to be applied. All that's good, not bad.*" (GC) (appendix 3A, table 4.2) along with the FSE. They discussed the results of the FSE and also the impact they had in terms of governmental policy in the form of further regulatory burdens for the farmer (GA appendix 3a table 4.2). They identified alteration to farming practice being an agricultural concern rather then a GM specific one (GA and GB appendix 3a table 4.2), highlighting herbicide management as a specific issue "*certainly herbicide tolerant GM crops by definition cause alterations to farm management*" (GD) (appendix 3A, table 4.2). Although they also mentioned the potential biodiversity implications, they discussed alteration in the context of the future of agriculture and what was wanted from farming, whether it should be food production or landscape management (GA appendix 3a table 4.2).

Like both the government and farmer groups, the industry group made reference to the potential benefits, seeing GM as a way for a farmer to extract more profit from the system by allowing them to "*manage their crops in an environmentally friendly way they can access other money. Therefore GM crops are already well set for that*" (IA) (appendix 3A, table 4.3). They also saw it as an agricultural issue rather than a GM specific one, stating all new agricultural practices will lead to alterations in farm management (IE appendix 3A, table 4.3) and drawing comparisons to chemical use and growing bioenergy crops in current conventional agricultural practices "*there are a lot of farming practices which have a negative effect on the environment*" (IC) (appendix 3A, table 4.3).

The NGOs, like the government, identified potential implications for biodiversity, stating that with GM "*these become more difficult to predict*" (NB) (appendix 3A, table 4.4) as GM might enable farmers to stop rotational agriculture in favour of

growing one cash crop, as with GM they will no longer have weed issues which require rotational farming practices. They also drew comparisons to current conventional practices like the industry group, but concentrated on the concern that GM could perpetuate the environmental risks already posed by conventional agricultural intensification (NG appendix 3A, table 4.4). The group in fact identified the potential GM has to further intensify and industrialise agriculture "*I think GM leads to the intensification of agriculture*" (NG) (appendix 3A, table 4.4); but they also acknowledged their own lack of knowledge about potential alterations GM could have.

The scientists overwhelmingly saw alterations to farm management practices as being an agricultural issue (SB, SC, SG and SI appendix 3A, table 4.5); linking agricultural change to government subsidy drivers (SB and SG) and the reliance on high input agriculture (SC). They felt that alterations due to GM should be seen in the context of agriculture "*to put GM in perspective*" (SG) and to answer "*the key question, whether GM will be better or cause change at all*" (SB) (appendix 3A, table 4.5). Although they did identify that GM does have the potential to generate implications for farm management practice, they caveat this by saying "*GM crops do change farming practices; we have not seen any changes that pose risks. We have seen changes that reduce risks*" (SE) (appendix 3A, table 4.5). They also identified the potential benefits GM could posses in relation to farm management especially in relation to the crops on the market now which can "*give you flexibility for biodiversity if that is what you want*" (SF) (appendix 3A, table 4.5). They also made reference to the FSE, which they questioned in terms of its narrowness in scope (SH appendix 3A table 4.5) identifying that "*the FSE were much more about management practices then it was about which technology you should use*" (SC) (appendix 3A, table 4.5).

3.3.3.2 Stakeholder group comparisons of themes

There were clearly some themes identified by numerous stakeholder groups (table 3.4). All bar the NGO envisaged GM crops to be potentially beneficial in to farm management practices. The government, industry and scientist groups identified

alterations to farm management as being an agricultural issue rather then a GM one. The industry and NGO groups made comparisons to current conventional practice; the government and NGO groups saw the potential for alterations to farm management to have biodiversity implications. The FSE was referred to by the government, farmer and scientists groups.

Using PCA, sixteen themes from the initial list of fifty three identified in the stakeholders responses, loaded either negatively or positively on to either of the two axis (appendix 3B, Table 4) representing 77.34 of the variation (figure 3.4A).

The government and scientists groups both scored positively on axis one and negatively on axis two; with five themes also loaded onto the axes in the same way (figure 3.4B). Both groups mentioned that alterations to farm management practices in an agricultural issue; and brought up the FSE (appendix 3A, table 4.2 & 3A.4.5). The other three themes differentiate between the two groups; with only the scientists group mentioning the inadequacy of communication, the need to consider the risks posed by GM in the context of agriculture in general, and the farm management implications. In terms of inadequate communication, the scientists group was concerned that often the scientific message was not well explained (appendix 3A, table 7.2); they also felt that while GM crops did have farm management implications these needed to be considered in the context of agriculture in general (section 3.3.4).

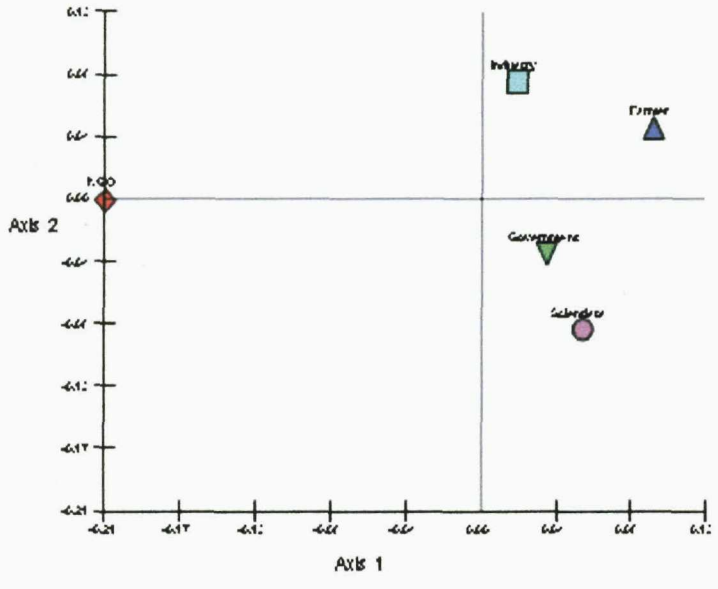
The industry and farmer groups scored positively on both axes, although to varying extents. The farmer response is best explained by the theme benefits; whereas industry response, which scores lower on axis one, featured the need to draw comparisons with current conventional practices (see section 3.3.4). The industry group were the only group who mentioned that an assessment of the farm management alterations brought about by GM crops was a requirement of the regulatory process (appendix 3A, table 7.1).

Two themes in particular correlated with the NGO group's position on the two axes. Firstly, the potential GM has in relation to altering farming practices to

further intensify or industrialise agriculture, and secondly a lack of personal knowledge about altering farming practices. Again both were key themes identified by the group and therefore have been discussed in detail above.

Figure 3.4: A) Stakeholder group positioning on the two PCA axes accounting for 77.34% of the variance in the responses to interview question RA1bd: alterations to farm management practices. B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes. Farmer= blue triangle; government= green inverted triangle; industry= blue square; NGO= red diamond; scientists= pink circle.

A)



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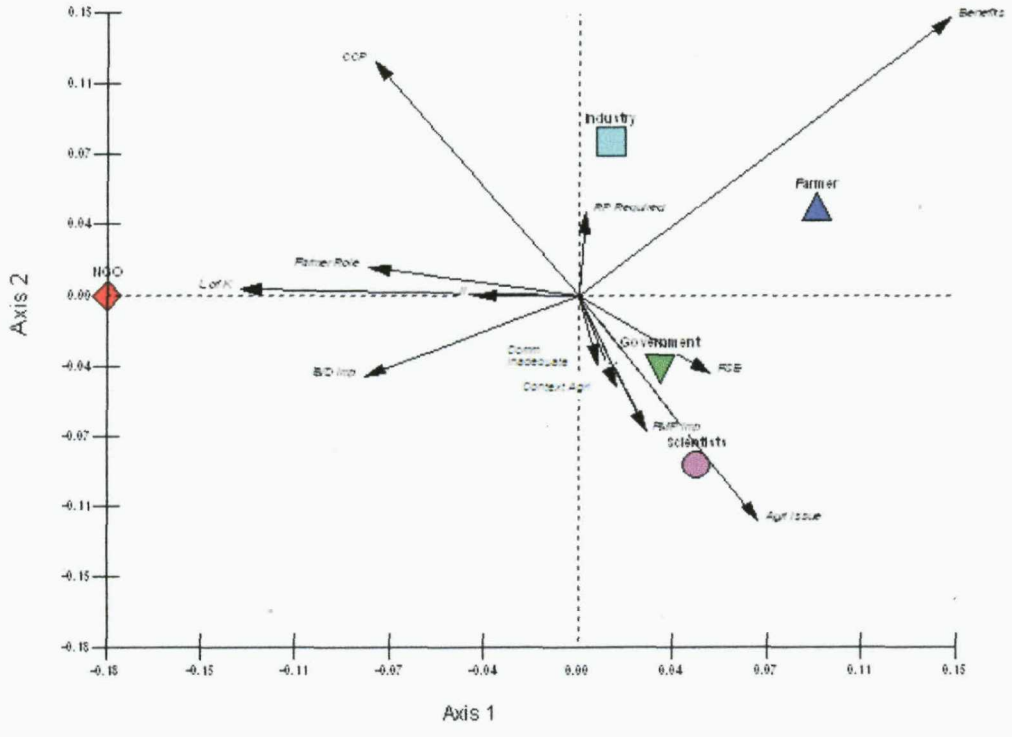


3.4 Discussion

When looking at the issues raised across the stakeholder groups in relation to their environment concerns (see sections 3.3), two points clearly emerge:

There are several key overarching issues which are raised by all stakeholder groups in relation to all of the research questions. These include: the need to compare GM with current conventional practices, to take a case-by-case approach in evaluating GM crops, that GM has the potential to benefit the environment and agriculture as well as pose risks and that the regulatory process is considered a good thing. These have been examined in detail (sections 3.4.1-3.4.5).

There are also a number of issues which are specific to an individual stakeholder group (section 3.4.8), in particular the NGO group (section 3.4.6). These differentiate between stakeholder groups' perceptions of the environmental risks posed by GM crops. They go some way to explaining why the current debate about the environmental risks of GM crops is so contentious and why some stakeholder groups do not accept that the current regulatory process adequately addresses the risks.

3.4.1 Comparisons with current conventional practices and the need to consider GM within the wider context of agriculture

All the stakeholder groups identified the need to compare GM crops with current conventional practices when discussing the environmental risks. However, the groups identifying this need differed depending upon the research question (table 3.5).

Table 3.5: The presence of the theme 'comparisons with current conventional practices' in the groups' response to each of the four research questions.

	Farmer	Government	Industry	NGO	Scientists
RA1a General Concerns	X	X			X
RA1ba Gene Flow	X	X			X
RA1bc Non-target Effects	X	X	X		X
RA1bd Alterations to Farm Management Practices			X	X	

All but the NGO group also identified that many of the environmental risks associated with GM crops were agricultural issues rather then GM specific risks. This was the central reason why the government, industry and scientists groups also stipulated the need for GM crops to be seen within the context of current agricultural practices.

The government, industry and scientists groups drew comparisons with conventional bred crops which have the same traits as the GM crops currently available. Their view was that herbicide tolerant, whether it was introduce via conventional breeding, or via GM, poses the same environmental risks, a point supported in the literature (Senior and Bavage, 2003; Dale et al., 2002b; Senior and Dale, 2002). This being the case, a regulatory system aimed at ensuring environmental safety and whose scope only covers GM crops, as it is processed based, is lacking in some respects. In short it neglects to safeguard the environment from comparable risks posed by different production mechanisms (ACRE, 2007). This 'imbalance' in the regulatory process stems from the underlying philosophy in Europe that GM crops pose novel risks and therefore require a separate regulatory process (EC, 2001; Gaugitsch, 2002). Other

regulatory processes, like the Canadian system, take a different approach to regulating GM crops. It considers the final product rather then the process of modification (Andree, 2002) and as a result any crop deemed to be a novel product needs to undergo the regulatory process. When discussing the need to compare GM crops with their conventional counterparts, one government stakeholder representative (GE) alluded to the benefits of the Canadian system and the potential to adapt the EU approach to be more in line with it: *"indeed the Canadians have a regulatory system which considers novelty rather then mechanism... ...I think there is an argument for saying that we should look at the consequences of new technologies in a more structured way than we have done in the past."* GE (appendix 3A, table 1.2). Under the Canadian system both conventionally and GM produced HT crops would be regulated, which seems a more appropriate method of safeguarding against what are essentially, or principally, the same environmental risks. The farming group took a slightly different tack, rather than seeing similarities in the inserted traits in GM and conventional crops; they saw similarities between the management strategies which could be employed to address the environmental risks associated with GM crops and those already employed to address similar concerns in conventional agriculture. They used high euricic acid rape (HEAR) in conventional practices to illustrate that coexistence issues occur with conventional varieties as well as those produced by GM. HEAR is a variety of rape used as an industry feed stock, however the high euricic acid content can cause liver lesions if consumed by humans (Chu and Higgins, 2001) so it needs to be kept separate from rape intended for human consumption. A number of coexistence measures are therefore in place to enable both to be grown without cross-contamination (Weekes et al., 2005). A number of sources in the scientific and regulatory communities seemed to share the view that coexistence *per* se should not be a stumbling block for GM commercialisation within the UK or EU, highlighting the coexistence measures in place in conventional agriculture (Brookes, 2004; Weekes et al., 2005). They felt that these coexistence measures could be adapted and applied to GM crops to address the issue of gene flow between neighbouring crops and related species appendix 3A, table 2.1). The NGO group on the other hand, when drawing comparison with current conventional practices differed from the rest. They highlighted the environmental risks that conventional agriculture poses and

discussed how GM crops had the propensity to perpetuate this. Thus rather than seeing GM as comparable to conventional practices in terms of the environmental risks posed, the NGO group saw it as a continuum of conventional agriculture, propagating, rather then reducing, environmental risks.

The need to draw comparisons with current conventional practices is clearly a key issue for the stakeholders. Indeed both the government and scientists groups go as far as to advocate the need to consider these risks within the context of agriculture in general, in terms of what is required from it (see Chapter Five, section 5.4.5). Under the current regulatory process (Council of the European Commission, 2001b; Council of the European Commission, 2004b) the risks are considered against a conventional comparator but only in relation to there being substantial equivalence (Millstone et al., 1999) (Chapter One, section 1.4.1). The results of the FSE found that there was greater difference in the biodiversity between crop types then there was between the GM and non-GM varieties (Firbank, 2003). So changes in conventional rotational practices, for instance the introduction of a new crop type (perhaps a bioenergy crop like *Miscanthus*), would have more affect on biodiversity then changing a non-GM variety for a GM variety (Firbank, 2003). In response, ACRE, the expert body for advising the UK government on releases into the environment, set up a subgroup to look at the wider implications of agriculture. In their report released on the 3rd of May 2007 (ACRE, 2007a) they identified the inconsistencies in the current regulatory process in terms of requiring in depth assessment only for GM crops and not other novel crops and practices which could pose similar environmental risks. It stated that "*to assess and manage more effectively the environmental footprint of agriculture as a whole, ACRE suggests that a broader and more balanced regulatory approach is required*" (ACRE, 2007a); going on to assert that novel crops produced through GM and non-GM methods need to be regulated and this assessment needs to include the benefits as well as the risks. The ACRE report signified that, at least at Member State level, these inconstancies within the regulatory process are beginning to be addressed. However, the impact the ACRE report has on a EU level is yet to be seen, ACRE seem hopeful that the methods they outline in their report "*could be accommodated in the European legislation concerning the*

deliberate release of Genetically Modified Organisms",(ACRE, 2007a). A second project commissioned by DEFRA as a result of the FSE was aimed at developing generic models to assess the risks posed by crop production practices (from this point forward referred to as the AR0317 project). These included the introduction of novel crops like GM and bioenergy crops; but also to assess changes in conventional agriculture and land use (Pidgeon et al., 2007). The findings of their project echoed those of the ACRE report (ACRE, 2007a); in that they stipulated "*the need to consider the biodiversity benefits of agricultural change as well as risks, so that the outcome is the assessment of biodiversity impacts rather then risk. This is the key to the ability to allow and manage change sustainably.*" (Pidgeon et al., 2007). This would certainly be a way to start redressing the imbalance in the current regulatory process, something all the stakeholder groups in this study identified.

3.4.2 The need for a case-by-case assessment

The need to consider GM crops on a case-by-case basis was also brought up by all the stakeholder groups at some point in their responses to the first three research questions (RA1a: general concerns; RA1ba: gene flow; and RA1bc: non-target effects). All the groups took the view that GM crops need to be considered in relation to their specific traits, the crop varieties these traits have been inserted into, and the receiving environment into which they are to be released. The crops need to therefore be considered on their own merits rather than under the umbrella of GMs. This is something which is mirrored in the regulatory and scientific assessment of the crops (Council of the European Commission, 2001b; Council of the European Commission, 2004b; EFSA, 2004).

3.4.3 The benefits

The benefits of GM crops were mentioned by all bar the NGO group, when discussing the environmental concerns relating to the non-target effects and alterations to farm management practices. The other groups saw GM crops as being, in some cases, superior to the technologies they are replacing, enabling the

farmer greater flexibility and the ability to reduce chemical inputs (appendix 3A, table 3.1, 3A.3.5, 3A.4.1, 3A.4.2, 3A.4.3 and 3A.4.5); which will aid farmers in achieving the environmental goals their subsidies now required (Martins and Marques, 2006). There has been a lot of debate in the scientific literature about just how much of an effect adopting GM cropping has on agro-chemical applications (Fernandez-Cornejo and McBride, 2000). General consensus is that it is highly dependant on the crop, the trait, abiotic factors like temperature and weather conditions, pest levels, spatial differences and temporal factors (Kirsten and Gouse, 2003; Marra et al., 2002). However the overall trend (globally) is that there is a reduction in pesticide reliance (Chu and Higgins, 2001; Fernandez-Cornejo and McBride, 2000; Huang et al., 2002; Kirsten and Gouse, 2003; Marra et al., 2002) with farmers switching from the organophosphates and organochlorides by 80% (Huang et al., 2002) and spraying fewer times per growing season (Qaim et al., 2003) (see Chapter One, section 1.3.1). The concern several of the groups raised is that regulatory hurdles are being placed in the way of the benefits of GM crops and this could have potentially environmentally detrimental effects. The risks of not adopting a technology are often not considered, yet are still valid concerns, especially for those who are the beneficiaries of the technology. Certainly the EU regulations (Council of the European Commission, 2001b; Council of the European Commission, 2002a) while not forbidding the assessment of benefits, does not explicitly require them; therefore benefits are often overlooked . The report by ACRE (2007a) makes a very valid argument for including the benefits and proposes using Comparative Sustainability Assessment (CSA) in order to explicitly assess the benefits. This, they felt, could be accommodated within the current European regulations in order for the benefits to be assessed (ACRE, 2007a).

The NGO group did mention the benefits of GM crops in their response to their concerns about gene flow; however their attitude towards the benefits differed dramatically from the other four groups. The NGO group were the only one who questioned the need for GM in the light of the risks associated with gene flow and the failure of the benefits to materialise. The benefits the NGO group identified as failing to be realised related to the grandiose claims made by some of GM

proponents, such as its ability, for example, to solve world hunger (appendix 3A, table 2.2). They are quite right to question the 'Silver bullet claims' which even advocates of the technology criticises (Scott, 2005); however, to dismiss the technology on the basis of its failure to achieve such unachievable claims is a little extreme. The other groups discussed GM's potential to achieve more realistic (environmental) benefits, to reduce certain pesticide applications or to give more flexibility to farm management (appendix 3A, table 3.1, 3A.4.1, 3A.4.2, 3A.4.3, and 3A.4.5). These more credible benefits were not mentioned by the NGO group, who instead focused on unachievable benefits; it would be interesting to examine whether the NGO group acknowledge these more attainable benefits to both the farmer and environment, or see them too as *"justifications by large companies who are making enormous profits"* ND (appendix 3A, table 2.5).

3.4.4 The importance of the regulatory process

Only the NGO group did not state the need for the regulatory process in their response to the four environmental risk questions. The farmers and government expressed the need for the regulatory process directly when discussing the environmental concerns in general (appendix 3A, table 1.1 & 3A.1.2); in order to avert the *"widespread release of something dangerous"* (FD). In the case of the industry and scientists groups the regulatory process filled them with the confidence that for already commercialised crops the associated environmental concerns have been evaluated and, where necessary, addressed (appendix 3A, table 1.3 & 3A.1.5). This illustrated the importance of the regulatory process, in the minds of the industry and scientists groups, to safeguard against environmental risks.

In the case of the industry group the need for the regulatory process was further articulated in their response as to whether they have any concerns in relation to gene flow; where the need for the regulatory process was identified as a key theme, (appendix 3A, table 2.3). The biotech industry's enthusiasm for their products to be regulated is not a new thing. Indeed it was industrial strategists in the US, primarily those from Monsanto, who pushed for the initial US

governmental regulation of the biotech industry in the 1980s. The reason given was that they hoped, by regulating GM, they would instil and build upon public confidence in biotechnology (Eichenwald, 2001; Schleircher, 2004) at a time when biotechnology was beginning to draw negative attention from some sections of the media in relation to the potential environmental and human health implications. It is not an unreasonable assumption that this was the motivation of industry, so as to quell unease about the technology. This is also one of the underlying aims of a regulatory process, in order too to instil confidence in the products which have been approved (Jaffe, 2004) (Chapter One, section 1.4). However the regulatory procedure is both time consuming and costly (Franks, 1999). Alternative suggestions as to the motivations behind why Monsanto lobbied for biotechnology to be regulated have been put forward. One motivation suggested by Schleicher (2004) was that by initially lobbying for regulations they might gain inside influence on the form the regulations would ultimately take. This is not an unreasonable suggestion; certainly the biotech companies do have influence over how the crops are now grown. For example, when it came to insect resistance the biotech industry built its own system for preventing its development (refugia strategy) which they presented to the Environmental Protection Agency (EPA) (one of the bodies responsible for regulating GM crops in the US, (Introduction Chapter One Section 1.4.3.1)). The EPA then imposed the conditions on growers of Bt crops to ensure compliance (Redick, 2005). This is beneficial for industry because if resistance does build up against the insect resistant crops currently on the market, these will become obsolete. Another motivation for industry to want their crops to be regulated is in relation to liability. One of the key arguments put forward by the producer when defending a liability suite is "*that the defect was attributable to compliance with regulations or national and international standards*" (Dewis, 1987). That is to say that if a product has gone though a regulatory process, then the producer of the product could plausibly argue that, "*the liability issue in question is attributable to the regulatory style* [scope]" (Mahdi et al., 2002). By being able to blame shortcomings in the regulatory process for not safeguarding against a risk, rather then the product for posing the hazard in the first place, liability does not solely fall upon the shoulders of industry. This certainly makes regulating the crops a more attractive prospect, to a multinational industry with concerns about potential

multimillion dollar liability suites. A more sinister motivation is the suggestion made by Henry Miller, (from the Food and Drug Administration (FDA) at the time the initial call for regulation biotechnology was made), was that Monsanto's initial calls for regulations were less about instilling public confidence and more to do with raising the barriers for smaller lesser-funded companies who, at the time. did not want their activities formally regulated by Washington (Schleircher, 2004). Whether this was the case or not initially will never be known; but the impact of the regulatory process on small biotech companies was exactly that; the costly process made it difficult for small biotech companies and publicly funded institutes to take a product through the regulatory process (McHughen, 2000). A number of companies have gone out of business or been taken over by larger companies; and as a result numerous traits have never, and will never, come to market (Maybeck and Bains, 2006) because the commercial value of them is not large enough to warrant the regulatory costs.

Independent of the role industry had in the origins of the regulatory process, the group are clearly familiar with the regulatory process and environmental risks evaluated within it. They have faith that the process works in terms of safeguarding against the environmental risks, which probably stems from their involvement in it (Chapter One, section 1.5.3), which gives the group insight into the depth and rigour of the regulatory process. Familiarity with a risk has been shown across a number of areas to reduce expert evaluations of that risk (Savadori et al., 2004). As the groups have been so heavily involved in evaluating the risks posed by each crop for the notification dossier they will be more familiar with the environmental risks posed than the other stakeholder groups, and as such, are more likely to perceive the environmental risks as lower, and the regulatory process as adequate for dealing with them. Familiarity with the regulatory process could also explain the confidence that the government and scientists groups had in it. The farming group are different as they are not as directly involved in the regulatory process and therefore will not be as familiar with it. In cases where people lack knowledge and familiarity with the regulatory process confidence usually stems from trust (see Chapter One, section 1.6.7). This would seem to be the case for the farming group who expressed their trust in the regulatory process,

the science it was based on and those scientists involved in it (Chapter Four, section 4.3.3)

3.4.5 Specific environmental concern over gene flow

Three stakeholder groups, government, industry and NGOs, raised specific concerns about gene flow and the implications this might have on the wider environment as well as the agro-ecosystem (appendix 3A, table 1.2, 3A.1.4, 3A.2.2 & 3A.2.3). The industry and NGO groups still differed in their responses, despite both identifying that gene flow is an issue specific to GM crops. When the industry group discussed gene flow they made the clear argument that gene flow is only a concern if the there are negative effects associated with the incorporation of the transgene into another plant, that gene flow *per se* is not a hazard in itself. They also make reference to the risk assessment process, which they felt considers gene flow carefully "*It needs to be carefully considered. I think it is carefully considered...*" (IB) (appendix 3A, table 2.3). The NGO group, on the other hand, did not make any distinction between whether the gene flow leads to negative environmental effects or not, they simply discuss gene flow *per se*. They also raised concerns about the safeguards in place to prevent gene flow (appendix 3A, table 1.4). It is clear that, while the groups were both concerned about gene flow, their concern differs dramatically, both in terms of the risks posed and in the way these risks are safeguarded against. Different methods will therefore need to be used to address the gene flow issue in order to satisfy both groups. This shows that even when similar concerns are raised, the disagreement still lives on (see section 3.5.4).

3.4.6 The wider concerns of the NGO group

The NGO group, when discussing the environmental risks, identified themes associated with much broader concerns, such as the ability for GM to further industrialize and intensify agriculture and the associated uncertainty with GM production (appendix 3A, table 1.4 and 3A.4.4). They noted that in relation to the

non-target effects, the regulatory process was too narrow (appendix 3A, table 2.4), which might be explained by their concern about these wider issues which are not covered under current regulations.

The post-war intensification of agriculture has often been criticised by NGOs; these criticisms centre on its reliance upon increased chemical and mechanical inputs as a way of increasing yield through cleaner, more efficient monoculture-based agricultural practices (Buguna-Hoffmann, 2001). The concerns about high input intensive agriculture are both environmentally driven, in terms on impacts on biodiversity, soil and water quality (Buguna-Hoffmann, 2001; Petersen and Hoogeveen, 2004); and ethically driven, in relation to the farmers' reliance on multinational chemical companies (Amendola et al., 2005; Friends of the Earth, 2007).. Environmental NGOs see GM as perpetuating this intensification of agriculture (Levidow, 2000) by enabling farmers to use broad-spectrum herbicides (in the case of HT GM crops) and essentially having a constantly active pesticide in the field (in relation to Bt and other IR GM crops). GM crops also extend the ethical issue associated with intensified industrialised agriculture. These issues include the role of multinational seed companies, the fact farmers are tied into buying both seeds and chemicals from one company when it comes to crops resistant to a specific herbicide. Further more, the farmers will also have to pay a technology charge on the seeds, and due to the intellectual property rights (IPR) owned by the companies, the farmers will no longer be able to seed save (a tradition synonymous with developing world agriculture) (Amendola et al., 2005; Herdt, 2006; Qaim and Traxler, 2005). Due to GM's potential to intensify and further industrialise agriculture and the ethical and environmental implications associated with this, the NGO group have "*...deep concerns about how it will further intensify agriculture, the effects that will have on the environment*" NF (appendix 3A, table 1.4). It is unsurprising that NGOs saw the potential for GM to intensify and further industrialise agriculture as an environmental concern, as in most of their mandates sustainability is a central objective (Buzzarri, 2007; Greenpeace, 2006; International Institute of Rural Reconstructions, 1999), an objective that the intensification and industrialisation of agriculture often contradicts, both environmental and ethically. When it comes to sustainability, in

terms of agricultural production, the organic model is the one pushed by the majority of the NGOs (e.g. Greenpeace (2006)). Organic farming has become synonymous with sustainable farming, which is seen by many as what we should be striving for in the future; even the government now have organic targets (DEFRA, 2004a). The organic sector has taken a strong anti-GM standpoint (The Soil Association, 2007) calling for strict threshold levels when it comes to coexistence and stipulating a policy of zero tolerance (Dale, 2003) (see Chapter Four, section 4.4.4). The Soil Association, a leading voice in organic certification in the UK, has had a particularly vocal role in the GM debate(The Soil Association, 2007) (Melchett, 1999).

The other big issue for the NGO group in relation to GM crops is the issue of uncertainty. Uncertainty has been associated with the production methods, the crops themselves and how they are utilised in agriculture. This has been a central issue discussed in the literature produced by NGO groups on GM crops (e.g. F of E, 2006). The issue the group raised in relation to the unknowns was that they could have "[unknown] *knock-on effects in the environment in a range of different areas"* (NE) (appendix 3A, table 1.4). While concerns about unknown effects transcend a number of environmental impacts, the underlying concern is consistently the same: there is a lack of scientific knowledge about the potential risks GM crops might pose, which results in "*...unacceptable levels of risk, unknowns associated with release. This would make release irresponsible as well as unacceptable"* (NF). With the group claiming that "*the scientific evidence underlying the uncertainty had got stronger year-by-year"* (NF) (appendix 3A, table 1.4). Certainly this is true, unknown and unintended effects of GM crops are being given more coverage within the scientific literature (Grove-White, 2006; Levidow, 2001; Levidow, 2003; Rogers, 2004; Schenkelaars, 2001; von Krauss et al., 2004) as researchers are identifying areas where research is lacking or where research needs to be directed. There has also been a lot of focus on the supposed "unknown, unknowns"; the uncertainties that as yet we are unaware of and against which, therefore, we cannot put into place any form of regulatory safeguards (Levidow, 2003). These unknowns are impossible to address through sound scientific research due to their very nature, as evaluating them cannot be

hypothesis driven, that is why those who site them also champion the Precautionary Principle as a way of addressing them. ((See (Levidow, 2003) for an insightful commentary on unknowns and the roles of both sound scientific evaluation and the Precautionary Principle). The question is whether the uncertainty associated with GM is any greater then that of any novel agricultural innovation or practice, and whether uncertainty linked to GM crops will result in greater environmental risks than the uncertainty associated with conventionally bred varieties.

In relation to the non-target effects, the NGO group raised the concern that the regulatory process is too narrow. They cited the need to question the ecological data presented, something which they perceived does not happen within the regulatory process (appendix 3A, table 3.4). In 2000 NGO groups challenged the placing on the National Seed Listing of Aventis GM crop variety Chardon LL (Alesbury, 2000; Meikle, 2000). Their primary concern was the duration of some of the scientific tests, which were required to last two years but ended up only lasting one (F of E, 2002). They used an obscure law under the listing to call for a public hearing; this uncovered a number of other anomalies with the scientific evidence passed by the scientific expert bodies regulating the deliberate release. In one of the studies twice the amount of chickens which were fed on the GM crop died as compared to the control (Friends of the Earth, 2002; Meikle, 2000). The result of the public hearing was that further scientific testing of Chardon LL would be required. This supported the NGO argument that the level of scientific evaluation at the regulatory level is inadequate. By questioning the scientific evidence and the scope of the regulatory process in general, the NGO group are focusing on the broader issues: in this case, what is deemed suitable when performing an ecological study; rather then questioning the findings of a particular study. It is clear that from their responses in relation to their environmental concerns about GM crops, the group focus on the much wider issues of uncertainty, intensification and regulatory scope. An argument could be made that these concerns relate as much to any non-GM agricultural practice as they do to a GM one, however it is GM agriculture which has drawn their attention, and thus

in relation to GM these issues need to be addressed, though perhaps within the context of wider agriculture.

3.4.7 Similarities in the key themes identified

When considering the themes identified across the research questions, several are identified by multiple stakeholder groups (table 3.6). A couple of trends are worth noting: Firstly, some groups seemed to identify similar themes more then others, for example the government group identified thirteen themes which other groups also raised; whereas the Industry and NGO groups only identified six. The stakeholder groups can be separated into two distinctive clusters: government (13) scientists (10) and farmer (10) in one group and industry (6) and NGO (6) in another; the former group being more likely to agree on the environmental issues then the latter. The GM debate is a highly polarised one, which is often depicted with industry at one end and NGOs on the other (Wolfenbarger and Phifer, 2000). It makes sense that the polar ends, industry and NGOs, who are less likely to compromise and more likely to have divergent views raise fewer key themes which are similar to those raised by the other groups. Within the debate the government group has tried to remain neutral (BBC, 2003) and as a result they can probably identify with some of the issues both sides have raised, (table 3.6 yellow boxes). The scientists group was selected to represent scientists working across the stakeholder groups (Chapter Two, section 2.1.2); so it is understandable that similar themes would be identified. The group does not identify with any of the key themes the NGOs raise across the four questions, despite including scientists who worked for NGOs. In terms of the farmer group, one might expect, perhaps wrongly, that as the end users of the product they should be more in line with industry. However, they tended to identify similar themes as the government and scientists groups, only twice raising the same theme as the industry group, (table 3.6). This would suggest that the group are taking a very balanced approach to considering the environmental risks, identifying concerns mirroring those of scientists and the government.

Themes		CCP	GF SIssue	C-b-C	FC/AC	RP Need	FSE	Benefit	B/D Imp	L of K	Agri Issue	Context Agri
RA1a General Concerns	**Farmer**	X		X		X						
	Government	X	X			X						
	Industry				X							
	NGO		X									
	Scientists	X		X	X						*	
RA1ba Gene Flow	**Farmer**	X								X	*	
	Government	X	X	X								X
	Industry		X			*						
	NGO							*				
	Scientists	X		X								
RA1bc Non-target Effects	**Farmer**	X					X	X				
	Government	X		X								
	Industry	X		X								
	NGO			X			X				*	
	Scientists	X						X				

	Themes	CCP	GF SIssue	C-b-C	FC/AC	RP Need	FSE	Benefit	B/D Imp	L of K	Agri Issue	Context Agri
RA1bd Alterations to Farm Management Practices	**Farmer**						X	X				
	Government						X	X	X		X	
	Industry	X						X			X	
	NGO	X							X	X		
	Scientists						X	X				X

*Table 3.6: The main theme:, either, brought up by multiple (two or more) stakeholder groups across in relation to the same research question (depicted by an X); or, themes brought up by multiple stakeholder groups across the four research questions but not in relation to the same research question (depicted by a *). For example both farmers and scientists recognised that the environmental risks were an agricultural rather than GM specific issue; however the farmers mentioned this in response to RA1ba and the scientists in response to RA1a. CCP= comparisons to current conventional practices; GF SIssue= gene flow is a specific issue; RP Needed= the need for the regulatory process; FSE= Farm scale evaluations; Benefits= the benefits; Agri Issue= an agricultural issue rather then a GM specific one; FMP Imp= might have implications on farm management practices. Themes highlighted in yellow are where the government group agrees upon the issue with either the industry or NGO groups (discussed below). The thick outlined boxes identify how the themes mentioned by the groups differentiate for the first three questions (RA1a: general concerns; RA1ba: gene flow; and RA1bc: non-target effects) as opposed to the last (RA1bd: alterations to farm management).*

The second trend is that a number of the themes that the stakeholder groups brought up in relation to the initial three research questions (RA1a: general concerns, RA1ba: gene flow, RA1bc: non-target effects), were not brought up in relation to the last (RA1bd: alterations to farm management practices); these themes have been boxed in table 3.6. The response of the groups seems to suggest they see the alteration GM could have on farm management practices differently than they consider the other environmental issues. This trend is particularly evident in the government and scientists group's responses. When looking at the themes identified by the government group in relation to the specific issues of gene flow (RA1ba), non-target effects (RA1bc) and alterations to farm management (RA1bd); clear distinctions can be made between the former two and the latter one. In relation to the issues of gene flow and non-target alterations, the group identified themes relating to the issues being specific to GM and that while they should be considered in relation to current agricultural practices, the need for case-by-case evaluation and regulatory assessment (in the form of management and monitoring for gene flow and in relation to non-target effects via GM trialling). On the other hand the group see alteration to farm management practices as much more an agricultural issue based around alterations to herbicide management, as identified in the FSE. The alterations GM makes to farm management needs to be considered, according to the group, very much in terms of what is wanted from future agricultural production. A reason the government group seems to make such clear distinctions might be that while gene flow and non-target effects have been incorporated within the European regulatory process and the risk assessment for GM crops since the early 1990s under Directive 90/220/EEC (Council of the European Commission, 1990a) and as such are commonly acknowledged as specific hazards associated with GM, the issues associated with altering farm management are relatively newly conceived in relation to GM. Only recently, guidance documents on post-market monitoring (Council of the European Commission, 2004b; EFSA, 2004; EFSA, 2005) have been formulated at the European level and these have still to be introduced in many of the national legislations of the Member States (Council of the European Commission, 2004a; Schiemann, 2006). There is a lot of debate about how these are to be implemented, especially in relation to general surveillance aspects (Council of the European Commission, 2004a; DEFRA, 2004b), which is aimed at

identifying unknown risks (hazards), many of which will be associated with the alterations to farm management induced by GM adoption. Because, in relation to GM, alterations to farm management is relatively a new risk concept, it might explain why it has not been considered in the same way by the government group as the more well established GM crop concerns of gene flow and non-target effects. The group might be hesitant to identify alterations to farm management practices as a GM specific issue, as it could lead for calls for greater inclusion of it within the regulatory process. This could be expensive to implement and could leave the current regulatory process open for criticism. The scientists group's response, like the government group's, seems to differ when discussing the risks GM could pose in relation to altering farm management practices. They too see GM as having the potential to alter farm management, as was shown in the FSE; however they identified altering farm management as an agricultural issue and that any alteration that GM could instigate should be seen within the context of agricultural practices in general. The group clearly perceived this to be an agricultural issue rather then an issue specific to GM. A similar argument to the one posed above for the government group could be made, as all the scientists interviewed would also have been familiar with the EU Directives and regulatory requirements, so they could use inclusion in the regulatory process to help distinguish between the environmental risks. Within the responses by the scientists to their concerns about farm management alterations, two things are clear (appendix 3A, table 4.5): firstly, they identify a real need to place the alterations posed by GM crops in the context of those which would be posed by any change to farm management; and secondly, they highlight the need to look at the bigger drivers behind agricultural alterations. The current drivers of agricultural alterations are identified by the group as being the economic forces which drive high input agriculture and the government policies which dictate subsidies and the social changes, which have resulted in a boom of organic farming and conservational practices. One quote epitomizes this: "*In response to subsidies and governmental issues as much as market forces and social changes, a lot of farmers have become organic growers or are now using conservation boundaries. Social changes can alter farming practices as well as the economics of it and government policy*" (SB) (appendix 3A, table 4.5). By being able to identify these 'bigger' drivers of farm management alterations it allows us the scope to make

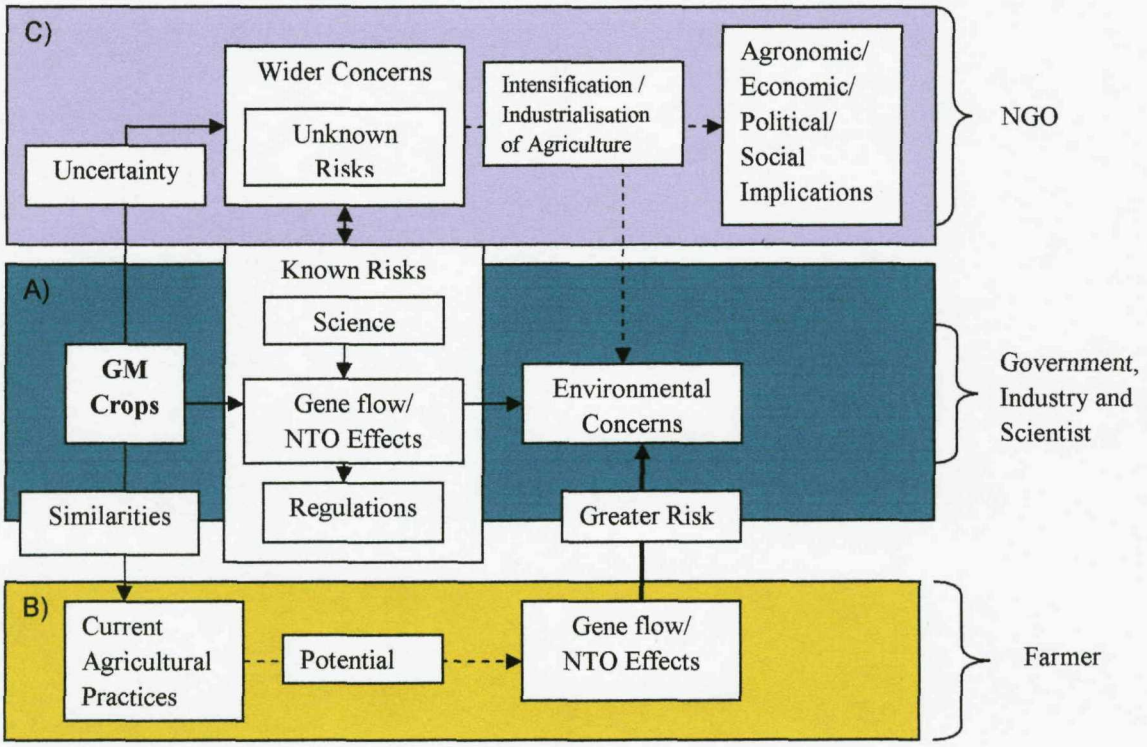
modifications in how farm management is altered in order to enable us/farmers/the government to reach the environmental goals which agriculture is beginning to be set (DEFRA, 2007a). The group makes the point that "*GM plants are only a minor factor of the management changing system*" (SG) (appendix 3A, table 4.5); indicating that if we want to make distinct positive alterations to farm management then we need to consider the bigger drivers and how GM might fit in with them rather than concentrating on GM as a specific issue (Chapter Five, section 5.4.5).

3.4.8 Differences between the stakeholder groups' responses

3.4.8.1 Environmental Concerns in General (RA1a)

The most obvious difference between the groups in terms of their environmental concerns in general is the tendency for government, industry and scientists to focus on the specific scientific and regulatory issues; whereas the NGO and farmer groups discuss their concerns in a much broader context. The differences in stakeholder group responses, when asked about their environmental concerns, are depicted in figure 3.5. It has been broken down into three sections A, B and C, which represent different areas or foci of concern and corresponds to the split between the stakeholders on the second PCA axis (figure 3.1B): with A being a neutral score, B a positive score and C a negative score. The government, industry and scientists groups focused their concerns on the GM crops and how they are scientifically evaluated and regulated (section A). The farmer group raised the issue of the environmental impacts conventional varieties pose and how GM crops need to be seen in relation to these (section B). The NGO group focused their concerns on the potential for GM to result in unknown risks as a result of the uncertainties attributed to the crops and their production methods. They also identify the potential for the crops to further industrialise and intensify agricultural production, which not only could have environmental implications but could also result in agricultural, economic, political and social impacts (section C).

Figure 3.5: The concerns the stakeholder groups raised in relation to their general environmental concerns and how these interrelate. Section A encompasses the concerns of scientists, industry and government, section B the concerns of the farmer and section C the NGO.



Familiarity and understanding of the science as well as the risks plays an important role in the differentiation between stakeholder groups. The government, industry and scientists groups are familiar with the regulatory process, and what are deemed to be the environmental risks of GM crops according to it (Council of the European Commission, 2001b; Council of the European Commission, 2004b; EFSA, 2004). Familiarity with a risk has been shown to reduce risk evaluation (Savadori et al., 2004; Scholderer et al., 1999; Sjoberg, 1998) and familiarity and involvement in the regulatory process instils greater confidence in decision based upon it (Slovic, 1992). Familiarity with the regulatory process could therefore be the reason behind the lack of environmental concerns stated by the industry and science group in relation to those crops already commercialised (Chapter One, section 1.5.3), as they have confidence in the regulatory process to safeguard against environmental risks (see section 3.4.4). It also suggests that the groups generally agree with the fundamental scientific basis the process is built upon, as well as perceiving that it addresses all the relevant environmental issues, which

could explain why they did not discuss the wider concerns which lie outside the present regulatory scope.

Within section A there is a split between the groups, which explains the differences illustrated on the PCA axis one (figure 3.1). The government groups focus on GM crops as a whole, not distinguishing between those already commercialised and future crops (unlike the scientists and industry groups); they also did not specify the need for a case-by-case appraisal of the crops. This is in some ways reflective of the regulatory process. When scientifically assessing the crops, the regulatory approach stipulates a case-by-case assessment, this does not negate the fact that GM crops, in general, are perceived by the process to pose potential environmental risks and therefore in need of regulating. This is especially evident when considering that crops produced through conventional methods displaying the same traits and thus posing similar environmental risks; these however do not require the same level of regulatory assessment. The regulatory process requires scientific evidence to prove the crops have been evaluated in relation to a set of specific concerns (gene flow, non-target effects etc) independent of the individual crop types or traits; granted that more detailed assessments will need to be made form some crops then for others, general consensus is that all GM crops have the potential to pose those risks. GM crops are, therefore, seen by the regulatory process as something distinctly different (Council of the European Commission, 2001b; Council of the European Commission, 2003b), which need to be evaluated against a specific set of environmental concerns and this has been reflected in the government group's response. The industry and scientists groups make much clearer distinctions between the crops, distinguishing between those crops which had been through the regulatory process and those which had not, as well as stipulating the need for a case-by-case appraisal of the crops. Both the industry and scientists groups clearly trust the regulatory process to safeguard against the environmental risks (Chapter One, section 1.5.7), which is unsurprising considering the roles in the process both have had (Chapter Two, section 2.1.2), thus familiarity with the process. Unlike the government group, the scientists and industry groups are not concerned about GM *per se*; their environmental concerns are trait and crop specific. This too could be a result of their familiarity with the environmental assessment of GM

crops and the scientific literature which dictates that different traits pose different environmental risks, thus the hazards posed by an HT crop will be different to those posed by an IR crop. Thus they identify with the need for case-by-case assessments of GM crops. This is not to say the government group does not make these distinctions; however they are the ones who need to implement the regulations, rather then perform the scientific assessment, and it is a lot harder to implement regulations on a case by case basis than it is to require *carte blanche* evaluations of GM crops.

The other two groups are a lot less familiar with the regulatory process in terms of their involvement in it, so it makes sense that their concerns do not focus on the regulatory process but are broader ranging and situated within a context they are familiar with. Indeed, NGOs have questioned the regulatory process in relation to its scope, which they feel does not adequately address all their concerns in relation to GM crops (appendix 3A, table 3.1 and 3A.3.4). Although the NGO group identified gene flow as a specific environmental concern, they concentrated on the wider issues relating to uncertainty, in particular scientific uncertainty, and the potential for GM crops to intensify and industrialise agricultural production (see section 3.6.4). The environmental issue/concerns which the NGO group raised are much broader then those covered within the scope of the regulatory process. While the regulatory process tries to minimise the scientific uncertainty it does not see it as a risk *per se* although it does include it as a reason to evoke the Precautionary Principle (Council of the European Commission, 2001b; Goklany, 2000; Levidow, 2001; Rogers, 2004) (see Chapter One, section 1.5.1). It is therefore understandable why the NGO group are so critical about the current regulatory process (Chapter Four, section 4.4.4) and ardent advocates of the precautionary principle. The need for the regulatory process to be more holistic in its approach to assessing GM risks is often an issue in NGO campaigns (NRC, 2002).

In the case of the farmer group they placed their environmental concerns in the context of agricultural production; seeing most of the potential environmental

risks as an agricultural issue rather then being a product of GM. They gave many examples of how conventional varieties can pose the same risks as GM crops (section 3.4.1) and this as a strong argument for the need to compare GM crops to current conventional practices when evaluating the environmental risks. The group's wealth of agronomic experience means they know the environmental issues associated with current agricultural production and already have to take numerous measures to minimise these risks. The experience of the farmer group has in agronomic production certainly makes them an expert when 'evaluation' the agronomic risks of GM crops pose, against those posed by conventional practices. The argument the farmer group puts forward raises a very valid point: GM crops and conventional varieties can have very similar traits and thus could pose similar risks (see section 3.4.8.2). The fact that a lot of money and time has gone into scientifically evaluating and regulating GM crops as well as mitigating against any environmental risks they might pose, suggests that potentially they could be less of a risk then a conventional crop. As conventional varieties are not regulated in the same way that GM crops are, scientifically, comparatively little is known about their environmental effects. There is definitely a move within the UK, on the back of the FSE, toward a more product-based regulatory approach like the Canadian system. This would bring GM more into context with conventional practices, or maybe the other way around, so as to treat conventionally bred varieties the same way GM varieties have been treated. The ACRE report (2007a) and DEFRA commissioned project "*Assessing the environmental impacts of crop production practice: beyond the GM crop farm-scale evaluation*" (Pidgeon et al., 2007) (see section 3.4.1) is evidence that comparisons are beginning to be made at a regulatory level between conventional and GM crops. The need to draw comparisons with current conventional practices is a re-occurring themes across all the research chapters (Chapter Four, section 4.4.5; & Chapter Five 5.4.5).

3.4.8.2 In relation to gene flow

The farmer, government and scientists groups all identified the need to draw comparisons between the risks of gene flow posed by GM crops and those posed by current conventional practices. This are, understandable, as a lot of the GM

traits which are currently available to farmers, which are also available through conventional breeding and therefore similar risks associated with the gene flow are likely from each (Senior and Bavage, 2003) (section 3.4.1). What differentiates the three groups is their positioning on the PCA axis one (figure 3.2). The government group identified gene flow as a specific issue of GM crops, however one which needs to be considered in the context of agriculture in general; whereas the farmer and scientist groups saw gene flow as an agricultural issue rather then one specific to GM; gene flow has happened since the dawn of agriculture and has enabled farmers and plant breeders to produce the crop varieties familiar to modern agriculture. The question is whether GM crops pose more environmental risks in relation to gene flow than their conventional counterparts. There are those who would argue that, due to the modification procedure, GM crops do pose more of a risk (Wilson et al., 2004); however there are more who would argue that it was highly dependant on the trait as to whether gene flow would have any environmental implications (Poppy and Wilkinson, 2005) and therefore, a conventionally bred and a GM crop that have the same traits incorporated would pose comparable risks (Senior and Bavage, 2003). This could explain the scientist group's position with regards to gene flow. The current regulatory system in Europe, however, sees GM crops as posing novel risks (Council of the European Commission, 2001b; Council of the European Commission, 2003b) and therefore requiring separate regulations. Gene flow is one of the areas required to be covered in the risk assessment under Annex III of the Directive (Council of the European Commission, 2001b). Because gene flow is seen by the regulatory process as being a specific concern in relation to GM crops, and as GM crops are seen as novel under the European regulatory system it is understandable why the government group have taken the stance that they have in relation to GM being a specific issue. The government group also saw the need to consider the risks posed by GM crops in the context of agricultural practices, something which has been reiterated by ACRE (2007).

Another theme which was synonymous with the government group's response was the need to consider liability issues. Liability, in relation to GM crops, has become a hot issue in Europe (ENDS, 2000; 2003) and its Member States (AEBC

2003). A large EU funded research program SIGMEA, has been funded in part "*to determine the social and legal responsibilities and liability implications of the introduction of GM crops into farming systems*" (Messean, 2007). Ministers and their advisors have played an important role in driving the European liability regulations (ENDS 2000; 2003) so it is not surprising that it has cropped up in relation to their concerns with respect to gene flow, especially as liability suites can be directed at the regulatory process as well as the crops themselves (discussed previously 3.4.4). The government groups view was that the polluter should pay (appendix 3A, table 5.1), which is the basis of the new updates to the European Liability Directive (ENDS 2007).

The NGO and industry groups differed from the other three, focusing on wider societal issues (section 3.4.6) and the role of the regulatory process; rather then the environmental implications of gene flow. Meanwhile, they discussed different concerns, directing their responses towards the same issues. Industry identified the need for the regulatory process, in relation to gene flow; to assess the human health and environmental implications (appendix 3A, table 2.3). While the NGO group questioned the processes' ability to safeguard against human error, the so called "*real world influences*" (NF) (appendix 3A, table 6.4), citing examples from Argentina and Brazil where unexpected effects, as a result of human actions, have had detrimental outcomes. When they discussed their concerns in relation to gene flow, both groups raised the issue of the science in relation to society. The NGO group questioned whether the scientific evaluation of risk, in relation to gene flow and coexistence issues, reflects societal concerns. They felt that the debate was, and is, too narrow in its focus; that the scientists and regulators want clear cut debates on single issues; coexistence distances was one example they highlighted. On the other hand, society are more concerned about wider all-encompassing issues of animal welfare, the types of food that we eat and the future of the countryside (appendix 3A, table 6.4). As a result they felt that the regulatory process is not adequately addressing the concerns of society: they used this to explain why society has sided with the anti-GM campaign when it comes to GM crops, as the anti-campaign has reflected their concerns (appendix 3A, table 6.3). The industry group, on the other hand felt the public lack knowledge about gene flow, and science in general, had resulted in them misunderstanding the risks

GM crops pose (appendix 3A, table 2.3). Their view was that if society had a better understanding of the risks and the science relating to GM crops, then they would be less concerned. This is a view held by those who support the knowledge deficient model (Chapter One, section 1.5.6.2), however recent studies have questioned the logic behind it (Durrant, 2006). These are two very different views of how society interprets the environmental risks GM crops pose in relation to gene flow. Probably the truth would be that they were both right: society are more concerned about the wider issues than they are about individual specific scientific risks; however society, also as a whole, lacks the quite specific environmental and scientific knowledge/ understanding which would allow them to evaluate for themselves the risks posed by gene flow from GM crops. There is definitely a need, therefore, for a two-pronged approach, addressing the divide between society and the science (Johnson et al., 2007). Society does need a better understanding upon which they can base their decisions, however as Durant and Legge identified (2006) people do not need to be educated but to be provided with unbiased information from which they can make their own opinion as to the merits of GM crop. They have scarcely received this from the media, industry or NGOs. There is also a need to ensure the public's concerns are heard and visibly addressed within the regulatory process, something which the regulatory process has been criticised for lacking (Davies and Wolf-Phillips, 2006; Johnson et al., 2007; The Royal Society, 2004). Public opinion, as discussed in the introduction (Chapter One, section 1.5) is a main driver of product acceptance. If the public do have concerns about the safety of an innovation, this need to be seen to be addressed; if they are not, then it is unlikely, no matter how thorough the scientific assessment is, that they will accept the innovation. Studies like "Uncertain World" (Grove-White, 1997) identified the public concerns prior to the real start of the debate in 1998 however at the time they were dismissed. Only with the 2003 GM Nation Debate (DTI, 2003) were the concerns given visible attention; however, the real agenda behind the GM Nation Debate and its usefulness have been questioned (Horlick-Jones et al., 2004; Pidgeon et al., 2005; Poortinga and Pidgeon, 2004). These two studies and others (Frewer, 2003) have shown that the core issues the public have with GM crops have not really changed, and they will not change until they are seen to be properly addressed. The NGO group were the only ones who questioned the need for GM in the light of the risks associated with

gene flow; they use Canada as an example illustrating some of the risks posed by GM crops in relation to the flow of transgenes (appendix 3A, table 6.4) and the failure of the benefits to materialise (see section 3.4.3). Both the industry and NGO groups question the agendas of the others, in relation to the environmental risks of gene flow. The NGO see industry having a vested interest and thus agenda. As they are able with GM crops to have "*farmers in an arm lock between the seeds and the chemicals*" (appendix 3A, table 6.4); in turn the industry group question the motives of the organic sector concerning the pragmatic stance it has taken in relation to GM contamination, (see section 3.4.6). The question of stakeholder agendas symbolises the polarised debate in Europe and the views each side have of the other.

3.4.8.3 In relation to the non-target organism effects

The NGO group was the only group which did not draw comparisons with the non-target effects posed by conventional practices, however they saw non-target effects as an agricultural issue rather then one specific to GM crops. The government's position however differed from the others who identified the need to draw comparisons with conventional practices; they saw the non-target effects as a specific issue of GM crops, in particular the insect resistant varieties, and one which required further trialling. As with gene flow, the effect GM crops have on non-targets has been a long running consideration in the EU regulatory process (Council of the European Commission, 2001b; Council of the European Commission, 2004b; EFSA, 2004), it is therefore understandable why the government group saw non-target effects as a specific issue of GM crops, as this is the regulatory standpoint. However this standpoint clearly is not in keeping with the other groups who see the risks very much within the context of current agricultural practices; with even the NGO group identified that non-target effects are more an issue of modern agriculture and need to be dealt with at this level (appendix 3A, table 3.4). Changes in the way non-target effects of agriculture as a whole are perceived at a regulatory level, is clearly what is required; the regulations need to be brought more in line with the stakeholders' concerns in order for them to be accepted as appropriate safeguards against environmental risks (Sjoberg, 1998; Slovic, 1992; Slovic et al., 2002). This is what is beginning

to happen in the UK with the ACRE report (2007) although whether this will be adopted at the European level has yet to be seen.

Apart from seeing the non-target effects as an agricultural issue, the NGO group took a very different approach in their response to the non-target effects GM crops posed. Rather than focusing on the risks themselves, they discussed the non-target effects in relation to wider issues as they had done previously (see section 3.3.3). In this case the NGO group made comparisons between the threats posed by GM crops and those experienced in the nuclear power disaster at Dounreay (appendix 3A, table 7.4). GM crops have been compared to nuclear power in the past by NGO groups campaigning against the deliberate release of the crop; Lord Melchett (of Greenpeace, at the time) used it as part of his defence for pulling up FSE crop trials (Kelso, 2000). As the group identified with these wider issues it is understandable that they should express concerns over the narrowness of the regulatory scope (appendix 3A, table 3.4). Both the government and NGO groups discuss additions which could improve the regulatory process when considering non-target effects: while the NGO group identified the need to broaden the regulatory scope, the government group stipulated the need for further trialling. This divergence of attitudes towards the way non-target effects should be addressed was seen during the FSE. While the government championed the trials: funding them, supporting the scientific protocols followed, and justifying their need; environmental NGOs bitterly opposed their sanctioning, claiming them to be irresponsible, specifically in respect to issues of coexistence and genetic contamination (Kelso, 2000). The government justified the trials by stating all the crops had passed regulatory approval in Europe and so gene flow and non-target effects had been evaluated, reviewed and deemed to pose insignificant environmental risks (Council of the European Commission, 2001b). The FSE were therefore required to look at the indirect effects the management regimes associated with the GM crops would have at a field level (Firbank, 2003), as this is something not addressed in the current regulations. This justification however is unlikely to have eased the concerns of the NGO group, who questioned the scope of the regulatory process in assessing the non-target organism effects (appendix 3A, table 3.4) and indeed criticised the government for allowing any deliberate

release of GM crops, whether that be for experimental release, as was the case for the FSE, or commercial purposes. The farmer group are the only one who directly discussed the FSE in relation to non-target effects; they raised their surprise at the findings of the trials (appendix 3A, table 3.1). The approach and methodologies of the FSE have been criticised by both sides of the debate (Ammann, 2005; Andow, 2003; Friends of the Earth, 2003d). This is reflected in this study: with the farmer group, seeing the benefits of the crops in relation to non-target effects, criticising the methodology for not allowing the benefits to be perceived; and the NGOs criticising their go-ahead due to inadequacies in the initial risk assessment and regulatory scope. This is something which ought to be addressed if the government wants future trialling of GM crops to go ahead in the UK without the NGO furore which surrounded the FSE, and that also reflect how the crops would be commercially used.

3.4.8.4 In relation to alterations to farm management practices

The greatest difference between the groups, in relation to their responses to how GM crops could alter farm management, is explained by whether they perceive GM crops to have the propensity to further intensify and industrialise agriculture; or whether they see GM crops as being beneficial. Unsurprisingly perhaps, the industry and farmer groups identified the potential benefits of GM crops when it comes to altering farm management practices. They saw GM's potential to reduce or negate a number of the negative environmental implications associated with modern agriculture (appendix 3A, table 4.1 and 3A.4.3) (The benefits these groups perceive GM crops to deliver have been discussed previously in section 3.4.3). Whereas the NGO group saw GM having the potential to further intensify, or industrialise, agriculture which would have detrimental environmental implications by negatively altering farm management practices. Indeed, this is how the results of the FSE were interpreted by some of the NGOs (GeneWatch, 2003b). Certainly GM crops have the potential to do both. For example the GM HT crops could enable farmers to use broad spectrum herbicides continuously, resulting in field barren of all weeds, which would be to the detriment of biodiversity; however they also give the farmer the ability to not use pre-emergent sprays, allowing over winter weed growth which would be to the benefit of

biodiversity and reduce soil erosion (Ammann, 2005). Thus the effect on the environment, alterations to farm management brought about by the utilisation of GM crops have, will be highly dependant on how the crops are used.

The industry group acknowledged that regulatory assessment of how GM crops might alter farm management practices, was a requirement under the new Food and Feed regulations (Council of the European Commission, 2004b) (appendix 3A, table 8.1). Yet four of the five stakeholder groups identified alterations to farm management as an agricultural rather then a GM specific issue, with only the NGO group not doing so. If the alterations to farm management are agricultural issues, then only regulating them in relation to GM crops suggests an imbalance in the regulatory approach. Most introductions, whether it is a GM crop, a bioenergy crop or a new conventionally bred variety, will result in some sort of change; this is beginning to be acknowledged and addressed by the government, who have commissioned the AR0317 project (see section 3.4.1). Agricultural change will more than likely have both positive and negative implications, so there is also a strong argument for the explicit incorporation of a benefit assessment too. There is, then, a need to consider both the benefits and the risks posed by current practices when making decisions about the impact that any crop will have; again this is something that has been identified in the ACRE report (2007a).

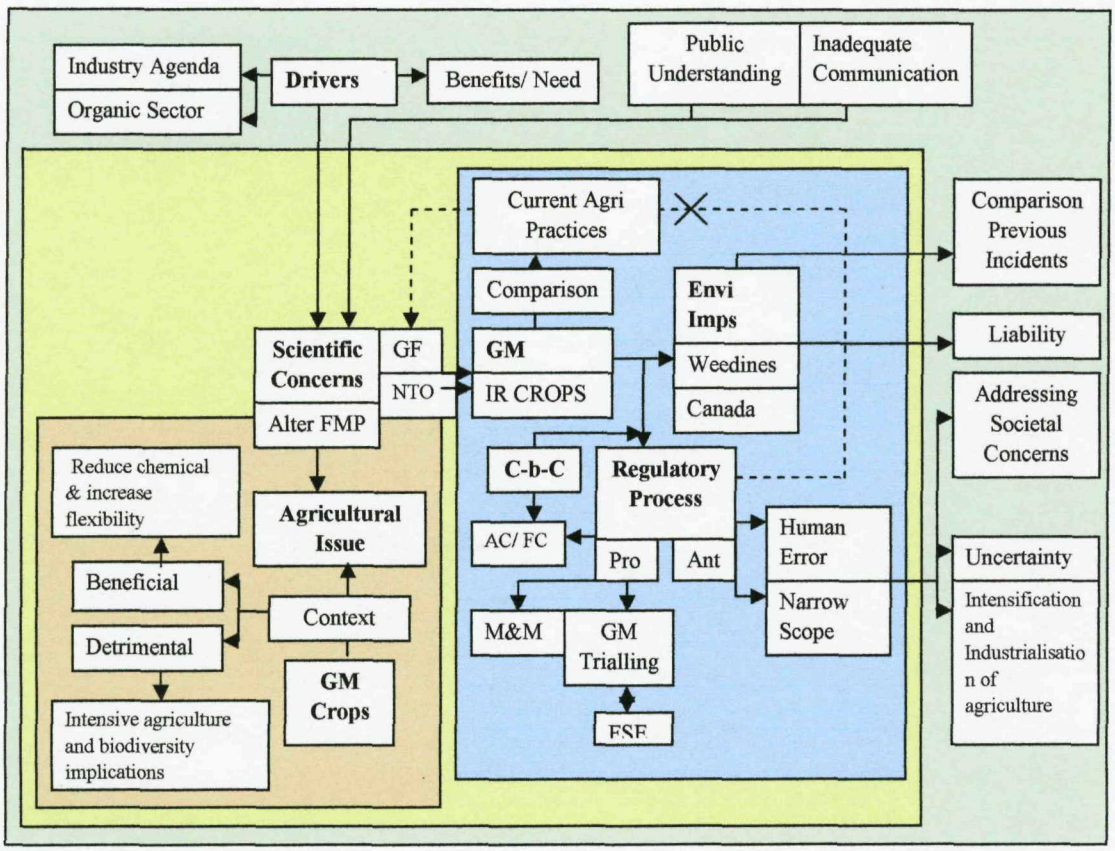
The scientists group were the only group to identify the inadequacy in the communication of the risks to farm management practice GM crops posed. They felt that the messages were not getting through to the public about the risks (appendix 3A, table 8.2); and the FSE provide a perfect example of this. For scientists, and those with an understanding of the scientific findings of the FSE, it was clear that the effect on biodiversity, while significant between the GM and non-GM variety was much greater when compared between the crop types, independent of whether they were GM or not (Burke, 2003). This shows that current agricultural practices such as rotating crops or sowing a new variety is likely to have a far bigger biodiversity effect than changing from a non-GM variety to a GM variety (Firbank, 2003). This is something the government group

also identified in relation to the potential for GM to alter farm management practices (appendix 3A, table 4.2); however, it was not presented in the non-technical report (Burke, 2003), which journalists and the public were referred to in the press release and on the DEFRA and ACRE websites (ACRE, 2007b; DEFRA, 2007b). In the DEFRA summary only one paragraph mentioned the difference between the crop types, "*however, the researchers believe that the differences in wildlife between the GM and the conventional crops could be similar to those found if a farmer changed from growing one crop to another. These effects could have been happening with changes in growing practices anyway, but researchers have not looked for them before*"(Burke, 2003). The rest of the 16 page FSE report discussed the difference between the GM and non-GM varieties and the implications the GM crops would have on biodiversity, and it was this message that was taken from the FSE by NGO (GeneWatch, 2003b).

3.5 Conclusion

While the stakeholder groups identified a number of issues in relation to their environmental concerns, four points in particular encapsulate the majority of these (figure 3.6): the way the risks associated to alterations to farm management practices were treated differently by the stakeholder groups; the need for GM crops to be considered in the context of current agricultural production; the role of the regulatory process when considering stakeholders environmental concerns (something which will be revisited in Chapter Four); and the fact that the debate still is very polarised. These will be revisited in the general discussion (Chapter Six).

Figure 3.6: The key themes identified by the five stakeholder groups conveying: a) the main environmental concerns identified by the groups and b) the themes which best represent the variation between the groups. Themes in the yellow box (including all those in the blue and peach boxes) relate to the scientific concerns and how these are regulated. Themes in the green box are issues stakeholders raise which are not scientific but are associated to the wider political/ethical/economical and societal implications the deliberate release of GM crops might pose. The blue and peach box separate themes brought up in association with the stakeholders' specific concerns towards gene flow, non-target effects and their concerns in general (blue box), and their concerns about farm management practices (peach box) as the stakeholder groups appear to consider RA1bd (alterations to farm management practices) differently to the others on the basis of the themes they identify. Arrows link the themes, unbroken lines are links which the stakeholders identified, broken arrows identify links put in by the researcher.



3.5.1 Alterations to farm management practices: an agricultural not a GM issue

Research question RA1bd (alterations to farm management practices) revealed a very different type response from the stakeholder groups than the other questions in this chapter. This was especially so in individual responses of the government and scientists groups, but also occurred when comparing the similar themes the stakeholder groups raised and the themes which represented how the stakeholder groups varied (see section 3.4.7). This suggested an underlying difference in stakeholders' attitude towards the risks posed by alterations to farm management as opposed to gene flow and non-target effects. The issues raised in relation to alterations to farm management would suggest the stakeholders see it more as an agricultural issue than a GM specific one (see section 3.4.1); one which needs to be address in relation to agriculture in general. Recent updates to the GM regulatory process, like the inclusion of general surveillance, have resulted in the need to now assess the environmental risks GM crops pose by altering farm management (Council of the European Commission, 2001b; Council of the European Commission, 2003b). A lot of money and time was spent in the UK evaluating the effect GM crops would have in terms of altering herbicide regimes in the FSE (Firbank, 2003). By only evaluating the risks associated with alterations to farm management posed by GM crops it confirms that the regulatory process sees GM as posing a novel set of risks (Council of the European Commission, 2001b), which is, in the case for how GM alters farm management, not representative of the stakeholders' concerns as identified in this study. This imbalance between how the stakeholders perceive the risks GM crops pose to farm management and how GM crops are regulated could have two effects. Firstly, the process could undermine stakeholder trust; as there have been clear links made between levels of trust an individual has in a process and how that process represents the individual's views (Chapter One, section 1.5.7). Secondly, by assessing only the risks posed by GM crops, there is the potential for them to be seen out of context. This could increase the chance that the potential benefits of GM crops could be missed. There is clearly a need to correct this imbalance between the stakeholders' concerns and what is considered by the regulatory process (see section 3.5.3). The environmental risks associated with altering farm management need to be considered for agriculture in general, not just GM. The

drivers and facilitators of agricultural change, as well as identifying what is wanted from future agriculture and food production, should be examined. Agricultural goals should be identified. These agricultural goals can be drivers of agricultural regulation, enabling agricultural change to be directed in a way which will enable agriculture to achieve the goals society sets it. With hindsight, such an approval process may have reduced the documented impacts caused to the environment by change in agricultural practice over the last 60-70 years. (Garces, 2002).

3.5.2 The need to draw comparisons with current conventional practices and consider the potential benefits

All the stakeholder groups identified the need to draw comparisons with conventional agricultural practices when considering the environmental risks posed by GM crops. Conventional varieties often have either similar traits (e.g. HT), or pose equivalent environmental risks (e.g. non-target effects of pesticide) (Senior and Bavage, 2003). By not considering GM crops in relation to the risks posed by conventional varieties, there is again the potential to see the risks of GM out of context and, as a result, in the prospective benefits of GM being passed up. This is something which is starting to be recognised; the ACRE report (2007) identifies the need not only to regulate both GM and non-GM crops but also to explicitly consider the potential benefits as well as the risks. Currently, while there is the scope to evaluate the potential benefits GM crops poses within the regulatory process, this is not taken up. Failure to identify the benefits means that some could be passed up. In order to identify the environmental implication of GM technology, the risks of not adopting GM technology (the missed benefits) need to taken into consideration alongside the risks of adopting GM crop. The potential benefits of GM crops were identified by the majority of stakeholder groups; as GM was seen as a way of reducing the farmers' reliance on chemical pesticides and aiding farming flexibility. Only the NGO group questioned the potential for GM to benefit agriculture and the environment; stating the failure of benefits to materialise. However the benefits they identify are some of the more extravagant "silver bullet" claims made by overzealous proponents of the technology (Scott, 2005).

3.5.3 The worth of the regulatory process

The majority of stakeholder groups are positive about the regulatory process in its ability to safeguard against the environmental risks. The scientists and industry groups gave it as the reason why they have no environmental concerns about those crops that are already commercialised; and the farmer and government group identified the need for the process in insuring against the general environmental risks, suggesting that, for the majority of stakeholders, the regulatory process is an appropriate and adequate way of safeguarding against the environmental risks GM crops might pose. The NGO group, however, took a very different stance: they have issues with the effectiveness of the process, as it fails to account for human error; they also question the regulatory scope. This is unsurprising as a lot of the issues the NGO group raise in relation to the potential environmental risks fall outside the scientific scope of the regulatory process; such as issues of uncertainty and the potential to further intensify and industrialise agriculture. These are as much agronomical, ethical, economic, political and social issues as they are scientific, so a scientific regulatory process alone will not satisfy the NGO group's concerns. If those involved in the regulatory process want the decisions based upon it to be accepted by the society as a whole, then they need to start to consider how it can address these wider issues; because, as the NGO group explain, these are the concerns with which the general public seem to identify.

3.5.4 The debate is still polarised

While there are some similarities in the areas of concern raised by the industry and NGO groups, such as the drivers of environmental concern and issues of societal risk perception, the issues these groups identify within these areas are distinctly different. When it comes to the drivers of GM crops and the potential environmental risks, the industry group blames the organic sector for using the risks associated with GM as a marketing ploy to boost organic sales (appendix 3A, table 5.2), in turn the NGO group question industry's agenda for pushing GM crops, suggesting industry see GM as a way of tying farmers to certain product (appendix 3A, table 2.1). In relation to society's perception of the risks: industry

feels that due to insufficient knowledge, society misunderstands the risks GM poses; whereas the NGOs feel society has different concerns about the risks GM pose than those covered in the regulatory process. As already mentioned, both groups have very different feelings about the worth of the regulatory process. The fact that there is such a divide in the debate means that it will be hard to make any changes that will satisfy both groups; a more holistic approach to regulating, monitoring and mitigating GM crops is required that attempts to address all the concerns, if not necessarily incorporating them.

Chapter Four

The stakeholders' perceptions of the regulatory process

4 Chapter Four: The stakeholders' regulatory concerns

4.1 Introduction

GM crops could be a useful tool in modern agricultural production, possessing a number of potential benefits for both agriculture and the environment (Altieri, 2001; John Innes Centre, 2003) (Chapter One, section 1.2). However along side the potential benefits (ABC, 2003; Burkhardt, 2001; Falk et al., 2002a; Roller, 2001), GM crops pose a number of inherent risks (Conner et al., 2003; Ford, 2004; Wolfenbarger and Phifer, 2000) (Chapter One, section 1.3), which need to be assessed and potentially addressed or mitigated against, prior to any commercialisation take place (Council of the European Commission, 2001b; Council of the European Commission, 2004b; EFSA, 2004) (Chapter One, section 1.4).

Worldwide, legislation has been put in place to regulate the applications of biotechnology. While globally there is huge variation in the regulatory requirements (Nap et al., 2003) (Chapter One, section 1.4.3) the central aim remains constant: to safeguard against harm to either human health and/or the environment (EFSA, 2004). The regulatory process in the EU (Council of the European Commission, 2001b; Council of the European Commission, 2004b) is regarded by many as being the most stringent in the world (Annerberg, 2003; Levidow, 2001); it has, however, also been heavily criticised by others, who raise concerns about its scope and the way applications for release have been reviewed (Friends of the Earth, 2004).

As a result of these divergent views about the appropriateness of the regulations, the GM debate has become more heated rather then less so, which contravenes one of the central objectives of any regulatory process: to ensure confidence in a product (Jaffe, 2004). This is an objective in which the current EU regulatory process falls short (Frewer et al., 2004). Without societal confidence in the

regulatory process, it is unlikely that there will general acceptance of the decisions that are made upon it (Chapter One, section 1.6.7). This has been demonstrated on multiple occasions in Europe for decisions regarding both Part B (experimental releases) and C (commercial releases) applications (Chapter One, section 1.4.1). The hostile treatment of the FSE in the UK illustrated society's reactions, when GM crops, which have passed regulatory approval, are release for experimental purposes. The voting of Member States against the opinions of EFSA (European Food Safety Authority) illustrates the lack of political confidence in the scientific review (see section 4.4.2).

See Chapter Three, section 3.1 for the approach taken to achieve the research aims (stated below) enabling the exploration of the stakeholders' perceptions of the regulatory process.

The three main aims are:

1. To identify the stakeholders perceptions of the regulatory process and their concerns

2. To compare stakeholder groups' perception of the regulatory process to uncover the similarities in their views and/or concerns. These can then be used as a starting point for stakeholder discussions relating the regulatory process, which will hopefully improve stakeholder cohesion. They also are clearly key themes which need to be addressed in relation to the regulatory process.

3. To compare stakeholder groups' perceptions of regulatory process to highlight the differences in their concerns. These can then be used to explain some of the polarisation already experienced within the debate, by gaining a better picture of what the differences are.

4.2 Methodology

The methodological approach has been set out in Chapter Two, (sections 2.2.4-2.4.3). This chapter investigates the stakeholder groups' responses to research questions:

RA2a: "*What are your thoughts on the current regulatory process legislating the deliberate release of genetically modified crops?*" (General opinion)

RA2ba: "*What do you think about the scope of the current regulatory process?*" (Regulatory scope)

RA2bb: "*What are your thoughts of the current review process an application for release has to undergo before it is approved?*" (Review process)

RA2bd: "*Are there any aspects of the current risk assessment process which, in your opinion, have room for improvement?*" (Improvements)

4.3 Results

The results section will be split into four parts corresponding to each of the interview questions. Each part starts initially with the identification of key themes for each individual stakeholder group using the "proportional occurrence" score method. It then goes on to draw comparisons between the stakeholder groups in terms of the similarities and differences between the group's responses.

4.3.1 RA2a: "What are your thoughts on the current regulatory process legislating the deliberate release of genetically modified crops?" (General opinion)

Table 4.1: The themes identified by each stakeholder group in relation to RA2a (general opinion). L of K= lack of knowledge; RP= regulatory process; Pol Role= the role of politics; S/H= Stakeholder; CCP= comparison to current conventional production; Comp B= comparison between.

	Farming	Government	Industry	NGO	Scientists
"proportional occurrence" score	L of K 0.501	Pol Role 0.349	Pol Role 1.088	L of K 0.280	CCP 0.418
	GM Trialling 0.244	S/H Inclusion 0.170	EFSA Role 0.687	CCP 0.198	RP Too Much 0.156
	Coexistence 0.225	ACRE Role 0.138	CCP 0.279	Coexistence 0.153	Comp B US/EU 0.107
	FSE 0.1	RP Product/Process 0.134		NO GMO 0.112	
	RP Rigorous 0.1	CCP 0.119		RP Too Much 0.109	

The farming group overwhelmingly identified their lack of knowledge in relation to the current regulatory process legislating GM crops (appendix four A, table 1.1). The main reason given was that they have no need to know about the regulatory process as "in this sector GM is not permitted" (Farmer B (FB)) and "*they* [GM crops] *don't directly affect our members*" (FA) (appendix four A, table 1.1). It should be noted that from this point forwards, any reference to individual stakeholders will be done so in an abbreviated form, using the first initial of the stakeholder group along with the letter which differentiates each individual in the group. So Farmer A, B, C will now become (FA, FB, FC, and so on). The farmer group did describe, however, the regulations as rigorous due to the "*considerable amount of scrutiny of the science applied to consider and evaluate those risks*"

(FI). The group also identified the importance of conducting GM trials as part of the regulatory assessment of the crops (*"I think a proper set of trialling should be done and carried out before anything is then put on a wider scale"* FJ); and their frustration at the crop trashing which occurred during the FSE (FG and FJ appendix four A, table 1.1); that, in their opinion, those responsible for destruction of the trial sites *"should be locked up"* (FJ). They blamed the openness of the regulations for the demolition of trials as *"it gave them the opportunity to target the areas, find out where the crops were, to hoe up the crops, all that sort of thing, it was a gift to them."* (FD). They stated their concern that the regulatory process allowed the six figure grid references to be published. The group also raised the issue of coexistence, notably by the organic farmers within the group. Their concern being that while *"we haven't had any problems with our producers saying 'what can we do, we have GM farmers next door?'"* (FB), so far this is because GM crops are not *"allowed anywhere at the moment. As it is purely on a trial basis"* (FB). The issue they have, is with the introduction of the 0.9% threshold under the new coexistence guidelines (Council of the European Commission, 2003a). The coexistence guidelines points Member States to the liability regulations (Council of the European Commission, 2003b), which sets the 0.9% threshold; the NGO group's concern is that *"once you have got to point nine all the science shows that once you have got to that level with replanting of seeds. Everything else escalates so it is very difficult to keep it at that level"* (FH). "It should be noted that contamination levels for seed stock (0.3% in cross-fertilising plants, and 0.5% in self-fertilising plants) are lower than the contamination levels of 0.9% which are allowed in the field for crop being grown for food and feed stock. The guidelines that regulate the commercial growth for food and feed, use the thresholds set in the liability regulations of 0.9%. Therefore,0.9% will be the threshold used from this point in the thesis onwards.',

The government group raised a number of issues relating to the roles of different stakeholders in the debate table 4.1. They questioned the role politics is having in the EU decision making process *"although it was designed as being an evidence-based, science-based system it has actually got a lot of political factors coming in"* (GB). Their concern is that *"all the decisions go to the Council of Ministers...*

where a number of Member States have been abstaining in the votes" (GB); as a result of this "*countries like Austria are making unilateral decisions about banning GM"* (GC). The group identified two concerns with the increasing political influence. Firstly, rather then basing decisions on the scientific "*comprehensive assessment of the behaviours of GM"* (GB), decisions are being based on political agendas of the different countries; and secondly, "*there is immense confusion about the powers of National Government and the power of the EU on approval of GM crops"* (GC). The group raised the roles of society, discussing stakeholder inclusion, which they also mention in relation to the role of ACRE (appendix four A, table 1.2). In general they identified the need for stakeholder contribution; "*I think that there is a valid role for lay people in committees like the human fertilisation and embryology authority where there are societal aspects"* (GE). When it comes to society's inclusion in the scientific evaluation, they stressed that their "*views will differ from many social scientists who say that the wider public should determine what it is the science does"* (GD). Their stance, is that the societal issues in relation to the scientific assessment are addressed and represented by the Ministers ("*They* [Ministers] *are paid to do the difficult non-evidence stuff that look at how this fits society*" GE). They questioned the role a layperson could have on one of the scientific committee ("*you stick a layperson in front of a four way analysis of variance and ask them to comment on it"* GE). Reiterating the point that "*it is absolutely vitally important that the scientists' independent scientists look at the science to evaluate the risks"* (GD), giving "*ACRE a clean remit to work in this way"* (GE). They did, however, identify that while "*the scientific advisory system in the UK... is good value for money and independent, it works"* (GE), it is "*criticised for many reasons depending on where you are coming from"*, citing examples of such concerns as: ACRE's links with industry, their lack of wider stakeholder inclusion and the issue of openness of meeting. The group also raised the issues associated with the regulatory process being process-based rather then product-driven, "*they* [GM crops] *are regulated in a special way because they have been produced through GM, rather then what the trait is of the crop. That is a fundamental principle which underlies the whole regulatory regime. That, from a scientific point of view, is a little questionable... it does mean that you will end up with inconsistencies like stopping GM herbicide tolerant oilseed rape from going on to the market but*

allowing non-GM varieties" (GA). The group called for the need to compare GM regulation to what is used for conventional crops; as the risks posed by GM are comparable with those posed by pesticides and the health risks associated with organic farming *"for instance the formation of mycotoxin in organic crops"* (GA).

The industry group overwhelmingly identified the role of politics in the regulatory process, raising concerns over the political motivation of the process (*"it is overridden by politics... ...politicians of course are driven by votes, ballot boxes and other factors. That would be my biggest grouse."* (IA appendix four A, table 1.3). Their feeling was that regulatory decisions were based on political interests (*"they are voting not on the science really but on the politics, they are sometimes given instructions some of them"* ID); and as a result, the regulatory process was evolving towards the political influences rather then the science (IA appendix four A, table 1.3). As a result, the process is becoming, *"incredibly time consuming... ...such that only a large multinational company can afford to get a product through the system"* (IE). The group also discuss the role of EFSA, and the issue that the view of EFSA is not always taken on board by the Member States: *"Some countries just don't believe them. They want to do the safety assessment for themselves, they can do that"* (IB). The group felt this was down to these Member States not being able to agree to any GM releases (appendix four A, table 1.3). They also questioned the criticism of EFSA having links with industry, *"certainly we don't see that. We can talk with them about our file though cannot meet with them unless it is over a specific issue to all companies"* (IB). Finally, the group identified the need to compare GM regulations with those governing conventional practices as GM *"regulations are over heavy compared to other things and the risks compare to other areas"* (IA), citing chemically modified or irradiated crops as posing comparable risks, (IC appendix four A, table 1.3). Their general consensus is *"that the regulations are fine, there does need to be a level playing field"* however *"if you used these same standards* [for non-GM crops] *it will probably be too strenuous"* (IC).

The NGO group, like the farming group, identified their lack of knowledge in relation to the current GM regulatory process (appendix four A, table 1.4), citing a lack of familiarity with the changes in the process. They also stipulated the need to draw comparisons with regulations governing conventional practices stating that *"this reflects more badly on how lax the regulatory system is in other areas, than that it is over the top for GM"* (NB). The group also questioned whether *"conventional non-GM crops are really what we want to take as the status quo or the yard stick so it is not really good in that respect"* (NC), suggesting that GM crops needed to be seen within a broader context, of where society wanted agriculture to be heading (appendix four A, table 1.4). The issue of the regulatory process for GM crops being too much was also raised by the NGO group *"we have a process which does require a lot of hoops to be jumped through... ...perhaps too many"* (NA). Coexistence was a specific issue raised by the group in relation to the regulatory process, they *"don't accept coexistence"* (NE) and question the adequacy of the regulatory process in preventing contamination (giving examples from North and South America) (NC appendix four A, table 1.4). They also expressed the wish to *"remain GMO free to prevail. I don't, as I said right at the beginning, see a place for GMO in agriculture"* (NE).

The scientists group also identified the need to make comparisons with the regulation of conventional crops. They saw the regulatory process of GM crops *"in some ways, incredibly over-the-top"* (SB); questioning this when, for conventional crops, *"there is almost no regulations for almost everything else a farmer does"* (SA), yet these can pose equivalent environmental risks (*"conventional practice which has such severe impacts on the environment should be subject to some sort of assessment process. It is bizarre that they are not."* SA). The group also drew comparisons between the EU regulatory process and the US, thinking *"both places address the questions"*. The group raised concerns over the lack of adoption in UK, which they perceive to *"have had impacts on the current amount of scientific work that can be done by academics or other sectors of science in those regions"* (SD).

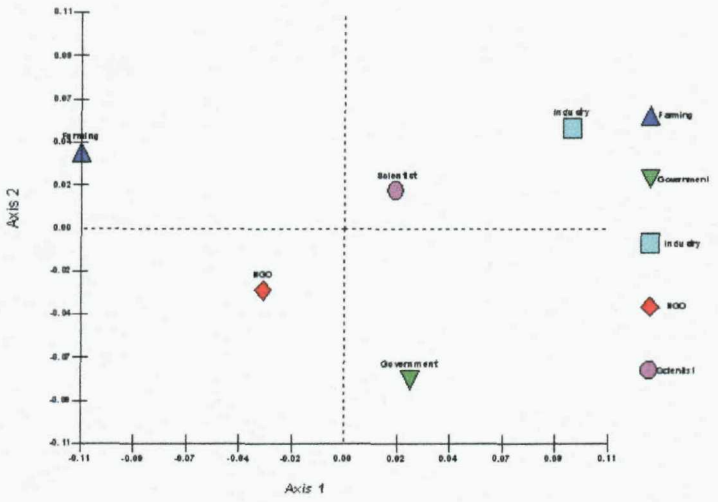
4.3.1.1 Stakeholder group comparisons of themes

Using the "proportional occurrence" scores, there are clearly some themes which are identified across stakeholder groups (table 4.1). All the groups, except the farming group, raised the need to compare the regulatory process required for GM crops to what is required for current conventional agriculture. The farming and NGO groups both identified a lack of knowledge in relation to the regulatory process and the specific issue of coexistence. The NGO and scientists groups identified that the regulatory process might be too much; and the government and industry groups discussed the role politics had played in the regulatory process.

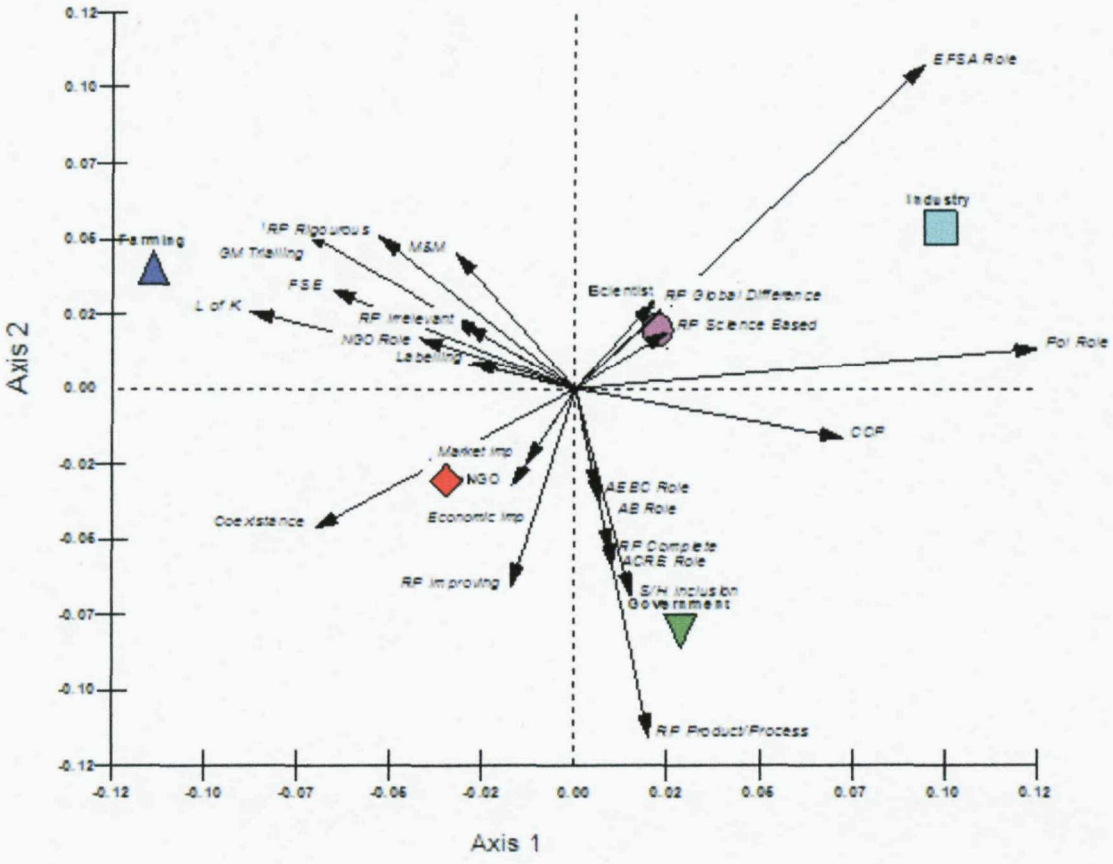
Using PCA, 65.60% of the variation between the five stakeholder groups' responses was explained by the two primary axes. Twenty three themes from the initial list of ninety three identified in the stakeholders responses loaded either negatively or positively on to either of the two axes (appendix four B, table 4.1). When considering the positioning on the axes, all the stakeholder groups were spread separately along the axes with very little apparent clustering of the groups (figure 4.1A). As all the groups scored either positively or negatively on both axes, a Euclidean biplot was used that mapped the themes in relation to their component scores on to the axes as well as the stakeholder groups (figure 4.1B).

Figure 4.1: A) Stakeholder group positioning on the two PCA axes (accounting for 65.60% of the variance in the responses to interview question RA2a, general opinion). B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes.

A)



B)



The industry and scientist groups loaded positively in relation to both axes, (figure 4.1B), suggesting these two groups responded similarly in relation to the themes that distinguishes between the two groups. A number of themes also scored on the axes in the same direction indicating the issues specifically raised by these groups. Both groups picked up on the global differences in the regulatory process, and that the regulatory process needs to be science based (appendix four A, table 5.2 & 4.5.4). The scientific group identified the differences between the regulatory processes in Western 'developed' countries and those in the developing world, citing the need to develop the regulatory process in developing countries (appendix four A, table 5.4). The industry group only compared developed world processes, which is unsurprising as the majority of their business is with these developed countries (James, 2005a). They saw similarities between many of these countries' regulatory processes, in terms of their "*basic principles of the safety assessment*" (ID), putting this down to international co-operation at the developmental stage (appendix four A, table 5.2). In terms of the process being science-based, the industry group questioned the point of jumping all the "*scientific hurdles*" (IE) when the approval decisions are based on the politics not the science. The group found this particularly difficult to comprehend as "*the EU is supposed to be a science-based economy.*" (IE). The scientific group agreed that the process should be scientifically rather then politically based (appendix four A, table 5.4). Both groups discuss the roles of EFSA and politics within the regulatory process (appendix four A, table 1.3 & 4.5.4), which they felt, to its detriment, was becoming more political: ("*a bad thing about it is that it has become tangled in politics*" (SA) "*politicians are not just voting on scientific safety assessments, it is the views of their country, their country's interest. Then it becomes difficult.*"(IB)). The industry group expressed concerns that the process was evolving towards the politics, rather then the science (appendix four A, table 1.3). In terms of EFSA's role, the scientific group was divided. The academic representative saw EFSAs role in making the judgements "*as a good thing*" (SA), a similar view to that of the industry group (appendix four A, table 1.3) who questioned the motivation of Member States that do not accept EFSA's opinions. While the scientific representative working within an NGO raised concerns about EFSA's role, feeling their opinions are "*without fail positive*" (SI) and questioning their use of the term "*not biologically relevant*", in relation to the definition of the

term (appendix four A, table 1.5); also questioning EFSA's dismissal of NGO concerns that are based on scientific evidence, when there is not scientific proof or even evidence to the contrary (appendix four A, table 5.4).

The NGO group loads oppositely to the scientists and industry groups, loading negatively on both axes. This indicates that the views of the NGO group are directly opposed to those of the other two; that themes raised by the scientists and industry group are unlikely to be mentioned by the NGO group, and vice versa. The NGO group raised the issues of economic and market implication; identifying the economic pressures which could be exhorted on EU farmers if they have to compete with others growing GM varieties (appendix four A, table 5.3). In terms of the market implications, they identified how the public's response to GM, rather then increasing regulatory legislation, has resulted in the supermarkets taking GM products off their shelves (appendix four A, table 5.3). Coexistence was a particular issues where the group felt the current regulatory processes were "*inadequate, were not going to prevent contamination*" (NC). They did, however, identify the improvement in the regulatory process; citing the inclusion of direct/indirect and immediate/delayed effects, as having improved the regulatory process in terms of its scope (appendix four A, table 5.3). These improvements, however, the group felt, had been driven by "*scrutiny from outside*" (ND) the regulatory process, rather then from within.

The government group scored positively on axis one but negatively in relation to axis two; as did a number of themes mostly relating to the roles of various advisory bodies and stakeholders. The way the groups viewed the roles of ACRE, politics and stakeholder inclusions have already been discussed in detail (section 4.3.1). In relation to advisory bodies in general, the group discussed the advisory process in the UK. They stated that "*they covered most areas*" (GD), but questioned whether they were joined up enough; as they have, in the past, been criticised about the gaps between the ACNFP (Advisory Committee on Novel Foods and Processes) and ACRE (appendix four A, table 5.1). In terms of the AEBC, the group questioned what the committee achieved, and the real motives

behind the public debate, which the AEBC claimed credit themselves for, *"I still retain some anxieties about it, about whether that was an appeasement process or whether it did enable effective communication"* (GD). The government group also cited the divergence between AEBC members (appendix four A, table 5.1). The group also clustered with two themes discussing the regulatory process. One related to the groups perception of the regulatory framework, which they felt to be complete, (*"the regulatory framework is almost complete, you could say"* (GF) (appendix four A, table 5.1)); and the other discussing the underlying product/process regulatory divisions (section 4.3.1).

The farming group scored negatively in relation to axis one yet positively on axis two. This suggested a divergence of views between the farming and governmental groups, although perhaps not as diametrical opposed as that between the NGO group and the scientists and industry groups (figure 4.1B). A number of themes scored in the same direction on the axis, most notably: a lack of knowledge about the regulatory process, the need for GM trialling and the fact that the FSE, as well as that the regulatory process, was too rigorous (appendix four A, table 1.1). These have all already been discussed in detail previously as they were key issues brought up by the group (section 4.3.2). The need to draw comparisons with the regulations required for conventional practices scored oppositely to the farming group on the biplot (figure 4.1B); this singles the farmers' group out from the others, as the only group that did not mention this is their response.

4.3.2 RA2ba: "What do you think about the scope of the current regulatory process?" (Regulatory scope).

Table 4.2: The key themes identified by each stakeholder group in relation to RA2A (Regulatory scope). CCP= comparisons with current conventional practices; L of K= lack of knowledge; P of V= point of view; RP= regulatory process; SE= substantial equivalence; SR= scientific research; R/B= risks and benefits

	Farming	Government	Industry	NGO	Scientists
"Proportional occurrence" Scores	CCP 0.426	EFSA Role 0.442	RP Evolving 0.292	L of K 0.310	SR Increasing 0.171
	L of K 0.111	RP Too Narrow 0.167	Public Understanding 0.185	SE 0.125	CCP 0.1
	P of V 0.111		L of K 0.167		Context R/B 0.1
	RP Stationary 0.111		RP Suitable 0.167		
			RP Scope 0.148		

The main issue identified by the farming group, in relation to their perception of the regulatory scope, was the comparison with conventional agriculture, in particular in terms of the trialling of new varieties and pest management strategies (*"we have trialled different rape varieties because we are trying to find, through that trialling process, a better variety to grow... we do lots of trials for other things: different herbicides, different varieties, all sorts of things, so why not GM as a comparator"* FG). They also discuss the regulatory process in terms of it staying stationary *"well today how much has it moved on over the last couple of years. Not a lot has happened then"* (FH). The group acknowledged their lack of knowledge and also caveat their opinions as personal points of view (appendix four A, table 2.1).

The role of EFSA was identified as a key theme in the government group's response; however there is an apparent split of opinion within the response. Whilst one of the group uses the EFSA guidance document as a way to justify the scope of the regulatory process "*EFSA request a complete set of data in detail, covering all kinds of aspects. I have a copy of the EFSA guidance documents for GM plants here*" (GG); another questioned the competency of the EFSA panel in assessing the environmental safety issue "*EFSA it is very small... ...I am not sure they have the competency. That really worries me actually... ...I am not sure there is sufficient balance in the GMO panel*" (GF). The group questioned the breadth of the regulatory process, using the FSE as an example of where the scope did not adequately address the concerns, "*I don't think the Farm Scale Trials... ...were sufficiently broad based. I don't think that the criteria assessed covered all the aspects that should have been.*" (GC).

The industry groups discussed the regulatory process as an evolving one, "*that science is never completely done...* however *...this doesn't mean that the previous stuff is invalid.*" (IA). They raised concerns over the levels of public understanding of the regulatory process "*they have been told that there has been no testing for harm to the environment... ...I think it* [the regulatory process] *has been a total surprise*" (IB). The group also mentioned how they felt the scope of the regulatory process is suitable ("*I think it is really all encompassing, it talks about selective advantages and disadvantages.*" (IB), "*I think the regulations are suitable*" IE) (appendix four A, table 2.3).

The NGO group identified a lack of knowledge when asked about the regulatory scope (appendix four A, table 2.4). The key issue the group did identify is the regulatory stance on substantial equivalence "*it is based on substantial equivalence, which is a fraudulent claim; it is a political construct, not a scientific one*" (NF).

The scientists group, like the farming group, drew comparisons to conventional practices when discussing the regulatory scope, *"the EU regulations are demanding much more from GM then any other crop used"* SG. They identified that conventional crops can pose similar risks and therefore *"you have to compare with current practices"* (SI). They also stressed the need to consider the risks in the context of the benefits, as *"you have to weigh the benefits also, this is not possible according to our legislation"* (SI). The benefits were something they felt *"the EU directive never asks for"* SG. Raising the point that *"it is normal in most* [other] *risk assessments to compare the risks against the benefits"* (SG).

4.3.2.1 Stakeholder group comparison of themes

Using the "proportional occurrence" scores, only two themes are raised across all the groups (table 4.2). The farming, industry and NGO groups identified a lack of knowledge when discussing the regulatory scope; while the farming and scientists groups identified the need to draw comparisons with the regulation of current conventional practices when considering the regulatory scope.

Using PCA, nineteen themes from the initial list of sixty eight identified in the stakeholders' responses loaded either negatively or positively on to either of the two axes (appendix four B, table 4.2) representing 67% of the variation. When considering the axes separately (figure 4.2A), industry clearly differed from the other four groups in relation to axis on scoring highly positively while the other groups scored negatively; the government group was separated from the others, scoring highly negatively on axis two, while the others score either positively, or in the case of industry only slightly negatively

The industry group when discussing the scope of the regulatory process, they felt it to be suitable, seeing it as an evolving process, one which has to match the science currently available (appendix four A, table 2.3). They raised questions about public understanding of the regulatory scope in terms of knowing what is required from the risk assessment (appendix four A, table 2.3). All these themes

also were identified as key themes for the industry group, so have been discussed above in detail in (section 4.3.2).

The government group clustered with several themes (figure 4.2B). They discussed the roles of: politics (appendix four A, table 6.1), stating that the regulatory scope has been "*affected by political pressure*" (GC); and EFSA (appendix four A, table 2.2). The group also raised a number of points in relation to what is required by the process, feeling that it is too broad and outlining the regulatory assessment (appendix four A, table 6.1). In relation to the process being too broad they identified "*the open ended nature of some of the requirements*" (GA), singling out the indirect and delayed effects as an example of this, and the implications this could have, "*creating difficulties for industry*" (GA). They were the only group who identified that we do not understand enough about ecosystems to answer some of the questions posed by the regulatory assessment (appendix four A, table 6.1): as "*we just don't have that sort of information... quite often the information is not actually knowable*" (GA).

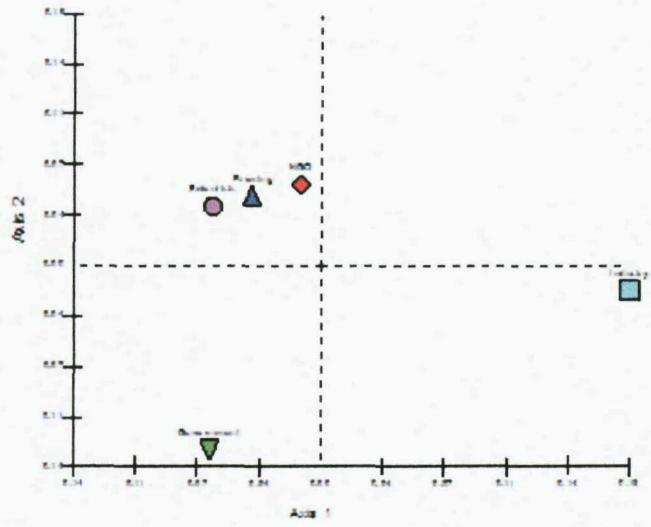
The industry group, when discussing the scope of the regulatory process, felt it to be suitable; seeing it as an evolving process, one which has to match the science currently available (appendix four A, table 2.3). They raised questions about public understanding of the regulatory scope, in terms of knowing that is required from the risk assessment (appendix four A, table 2.3). All these themes, also, were identified as key themes for the industry group, so have been discussed above in detail in (section 4.3.2).

The other three stakeholder groups clump together (figure 4.2B), indicative that they do not differ that much in relation to their views of the regulatory scope. However they can be separated in terms of their response by a number of group-specific themes, which cluster alongside them. The need to draw comparisons with conventional practices was cited by the farmer and scientist groups. As already discussed, the farmers saw a need to trial GM crops in order to compare

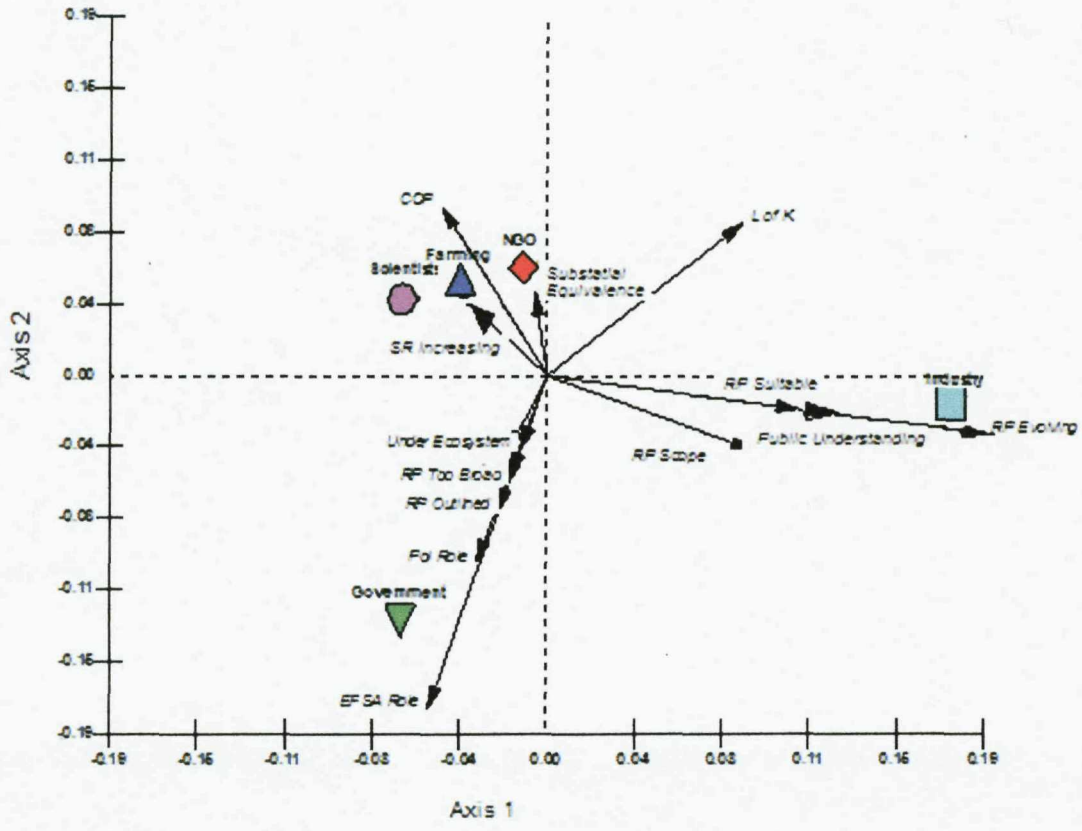
them to conventional varieties; whereas the scientists group envisaged conventional crops to pose comparable risks to their GM counterparts, thus requiring equal regulation. The issue of Substantial Equivalence was brought up specifically by the NGO group (appendix four A, table 2.4). The scientific group noted that the amount of scientific research available to the regulatory process is increasingly enabling the regulatory process to have greater capacity to evaluate GM crops (appendix four A, table 2.5). Both the NGO concerns about Substantial Equivalence and the scientists' discussion of increasing scientific research and capabilities have been discussed in detail above.

Figure 4.2: A) Stakeholder group positioning on the two PCA axes accounting for 67.02% of the variance in the responses to interview question RA2ba (regulatory scope). B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes.

A)



B)



4.3.3 RA2bb: "What are your thoughts of the current review process an application for release has to undergo before it is approved?" (Review process)

Table 4.3: The key themes identified by each stakeholder group in relation to RA2bb (review process). L of K= lack of knowledge; RP= regulatory process; CCP= comparisons with current conventional practices; M & M=management and monitoring; Pol= Political.

	Farming	Government	Industry	NGO	Scientists
"proportional occurrence" Scores	L of K 0.467	RP Notification 0.537	Pol Role 1.51	L of K 0.8	RP EU/US 0.260
	Scientists Trust 0.3	L of K 0.157	RP Consistency 0.12	EFSA Role 0.167	RP Global Differences 0.187
	RP Thorough 0.167	Benefits 0.143		RP Poor 0.167	EFSA Role 0.180
		RP Improving 0.137		Contamination 0.1	Pol Role 0.104
		CCP 0.127			
		M & M 0.106			
		RP Too Early 0.1			

While the farming group identified short comings, i.e. a lack in their own knowledge (appendix four A, table 3.1), they felt that the regulatory process is thorough "*I am convinced that it has been thoroughly tested*" (FC). The group compensated for this lack by having trust in the scientists "*I would quickly like to say that as a farmer you tend to accept that the scientists do the work behind these regulations. That good science is being applied. You trust the scientists*" (FE). They also discussed the breakdowns in trust between society and the regulatory process, "*we live in a cynical world*" (FE), "*they* [the populous] *tend to have a cynical view of them, in as much as anything else, because they don't understand*

the science or the background to the subject" (FI); identifying *"the populous is suspicious of these committees; they tend to view the people on them as being somewhat privileged in many ways, over rewarded for what they do"* (FI).

The Government group identified a number of issues. They discussed what is involved in the notification procedure (appendix four A, table 3.2), and that *"it is too early"* (GF) to make judgements on the notification procedure as this has recently changed with the introduction of the Food and Feed Regulation under this *"the applicant have two possibilities; they could use the old Directive or they could use the new regulations to file their applications"* (GF), therefore they need time in order to assess the effectiveness of the new regulatory procedure. They did however see the regulatory process in terms of the notification procedure as improving *"there are a lot of changes which have been good"* (GF), *"it has streamlined* [the process]... *...I think it is clear, more logical"* (GA). The group discussed the need to incorporate the benefits and to draw comparisons with current conventional practices in terms of how they are reviewed (appendix four A, table 3.2) citing the need to look at *"how does this* [GM crops] *impacts compare with other solutions of the problem it is there to solve"* (GA). The group also discussed the issues of monitoring and managing GM crops, in terms of managing GM crops they identified the need to set management requirements based on the crop in question (GD appendix four A, table 3.2). When it came to monitoring their view was that *"the whole monitoring part that was really lacking,"* questioning the need for monitoring unknown unknowns (*"which in my view is entirely unmanageable, hopelessly bureaucratic and would effectively keep GM out of the European market"* GD).

The industry group raised two points, which are closely related. One surrounding the need for regulatory consistency (appendix four A, table 3.3) and the second in relation to *"what many in the industry and the international community would regard as political influence"* (IB). They gave examples where the politics have influenced the notification procedure (IB and IE appendix four A, table 3.3). As a result of the political influence *"very often there are time delays"* (IA), which the

industry say they "*are prepared to work through that, once we know what is required... as long as they know in the end that if they put in the effort, work, money and information you need for the risk assessment, then the work will pay off*" (IC).

Then NGO group cited their lack of knowledge in relation to the notification procedure (appendix four A, table 3.4); they do however raise a number of concerns. One is the centralised approach to reviewing notification dossiers for release, primarily in relation to the role of EFSA, "*which I think is a worry on an environmental assessment point of view... ...there is only one ecologist on the panel at the moment*" (NC). Because of the centralised approach and reliance on EFSA, the group perceived there to be an "*issue of confidence around the environmental risk assessment at the moment*" NC. They also raised issues over the rigour of the regulatory process in terms of its assessment of the notification documents; citing the Chardon LL case as an example of where the "*process of scrutiny was insufficient*" (ND). The group also raise the issue of contamination as they are "*convinced that it is not possible to contain these things... ...as far as I am concerned any application which is successful is one too many*" (NE).

The scientists group raised the point that the notification process differs globally, "*it has evolved from existing legislative frameworks. It is inevitably going to have inefficiencies*" (SB). They draw particular attention to comparisons between the EU and US procedures "*both countries are very good*" (SF) "*the EU models is held up as an exemplar of the Precautionary Principle. It is overriding. I think that will have to change. The problem with that one* [EU approach) *I have already outlined in terms of it being hard to handle large numbers of submissions. The US system is more able to handle large numbers of submissions. There is a problem with the lines of responsibility across different lines of authority.*" (SB). The group also talked about the role of EFSA in relation to the notification process; here the views of the group differed. Some saw "*a central EU body as a very good thing... ...it has people from different EU countries on it which gives in multiple perspectives... ...you can gain a much broader perspective and this has improved*

risk assessment" (SA) while others question "*having a Food Standards Agency doing environmental risk assessment. These people are not ecologists in any sense of the word. They need a separate ecological risk assessment group that does that.*" (SI). The role of politics in the review process is also questioned, as "*in Europe we have seen may times that they cannot come to an agreement*" (SF), the group perceived a lot of the criticisms of the current regulatory review procedure "*are less to do with health and safety and more to do with political issues*" (SC).

4.3.3.1 Stakeholder group comparison of themes

The farming, governmental and NGO groups identified a lack of knowledge when it came to the regulatory review process. Both the industry and scientists groups discussed the role of politics in the review procedure and the NGO and scientists groups consider the role of EFSA in the procedure.

Using PCA, twenty themes from the initial list of sixty three identified in the stakeholders' response loaded either negatively or positively on to either of the two axes (appendix four B, table 4.3) representing 71% of the variation. In relation to axis one, both the industry group and the scientists scored negatively (scientists group to a lesser extent), whereas the NGO group scored highly positively as did the government and farming groups positively again but to a lesser extent (figure 4.3A). In relation to axis two, the farming, government and scientist groups all scored positively, the government group slightly more so; with the industry and NGO groups scoring negatively, the NGO group to a great extent.

There are three distinct clustering of themes (figure 4.3B), with the scientists group seemingly set apart. The diametrically opposed positioning of the scientists and NGO groups suggest that their concerns in relation to the regulatory review process are conflicting.

The NGO group stipulated a lack of knowledge in relation to the review process; they are concerned about the potential for GM contamination (appendix four A, table 3.4), and the inadequacies of the previous regulatory process in dealing with contamination risks (section 4.3.3). The group raised specific concerns about the regulatory process being founded upon the basis of substantial equivalence (appendix four A, table 7.3), *"if you don't think these things are substantially equivalent, then you want another process starting from somewhere else, following a different route"* (NF). They saw this as a reason why the regulatory process has been, in their opinion, unsuccessful in reassuring the public. The group also stated their view of the review process as poor; mentioning EFSAs, criticising its central role in the review process and questioning its competency (appendix four A, table 7.3).

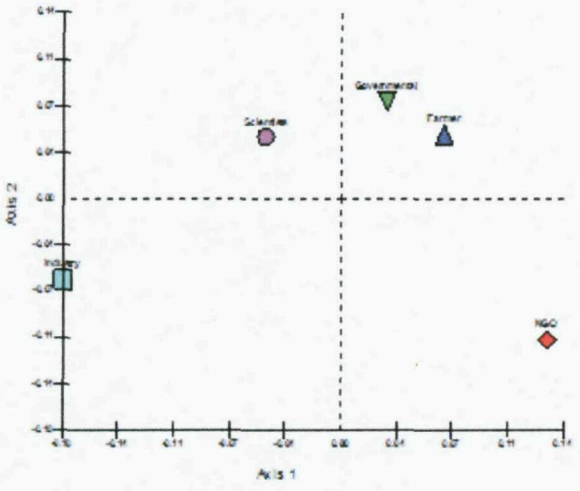
The scientists group view was more in line with government and farmers in terms of axis two, and industry group in relation to axis one; however no tendency to compare EU and US regulatory approaches to the scientific review of release applications (appendix four A, table 3.5), set the scientists group apart. The group highlighted the difference between the two systems (see section 4.3.3).

The government and farming groups' clustered together, scoring positively in relation to both axes; alongside a number of themes. The government group identified the need to include benefits that could potentially *"off-set the adverse effects on the environment by saying there is a benefit"* (GB). Both groups perceived the regulatory process as being thorough (appendix four A, table 3.1 & 7.2) and in the case of the governmental group, robust (appendix four A, table 7.2) *"it would be hard to see how you could actually do more"* (GA); outlining the notification procedure. The farming group stated their trust in the science which underlies the regulatory process and in the scientists who are involved in reviewing the notification dossiers (appendix four A, table 3.1).

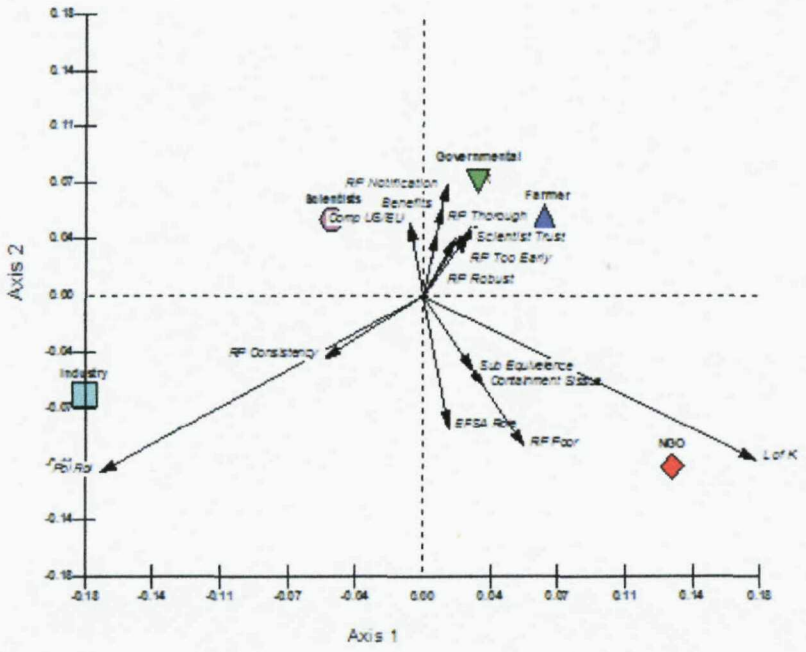
Two themes, the need for regulatory consistency and the role of politics load on the axes in an opposite direction to the farming and government groups (figure 4.3B), suggesting these concerns are not ones these two groups have in relation to the review process. They do however correlate with the industry group's response, and were identified as key themes by the group and as such have been discussed, see section 4.3.3.

Figure 4.3: A) Stakeholder group positioning on the two PCA axes accounting for 70.64% of the variance in the responses to interview question RA2bb regulatory review process. B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes.

A)



B)



4.3.4 RA2bd: "Are there any aspects of the current risk assessment process which in your opinion have room for improvement?" (Improvements)

Table 4.4: The key themes identified by each stakeholder group in relation to RA2bd (improvements). L of K= lack of knowledge; Pol= Political ; Ind= Industry; FC=future crops; RP= regulatory process.

	Farming	Government	Industry	NGO	Scientists
"proportional occurrence" Scores	L of K 0.865	FC 0.143	RP Science Based 0.294	RP Regional 0.524	L of K 0.229
	Pol Role 0.316	RP Evolving 0.132	RP Consistency 0.25	L of K 0.333	RP Too Narrow 0.184
	Ind Role 0.114		RP Societal Issue 0.133	Transparency 0.289	Context Agriculture 0.115
	GM Trialling 0.106			Sustainability 0.1	RP Evolving 0.111
	Unsure 0.1				

The farmer group expressed their lack of knowledge in relation to the potential for improvements to be made to the regulatory process. Stating that they "*don't know enough about the details of them*" (FA). They did however identify the role various stakeholders have had in the debate as one potential area for improvement. In relation to the political role, they saw a need for government to "*oversee the trials independently as they are the only body who could independently trial or fund one*" (FJ). They criticise government policies for being "*a bit short term*" (FF) giving the energy bill and treatment of Foot and Mouth in the UK as examples of this. Identifying the need for "*the government to set a framework basically; this is what we should be working towards.*" (FF), they felt government should take more of "*a role in reassuring people*" (FE). When discussing the role

industry should have in the regulatory process, the group expressed concern over the control they already have (appendix four A, table 4.1) especially in terms of its effect over developing nations "*It is very easy for these technologies to be brought in almost under coercion in these countries*" (FH). The group also identified that there will "*always be the accusation that they would find that result wouldn't they*" (FJ) if industry was involved in the trialling of GM crops.

The government group stressed that "*you shouldn't look at this* [regulatory process] *as something which is fixed, it is a continually developing process*" (GE) seeing the regulatory process as one which "*always has room for improvement. It is an evolving process; regulations have to evolve. It has to meet new scientific challenge*" (GD). They also identified that in the case of future GM crops, one with novel traits like the insertion of new metabolic pathways or tolerance to abiotic stress, the regulatory process will need to be adapted so it can address these issues (appendix four A, table 4.2), which links to their view of the regulatory process as an evolving process.

While the industry group felt that the regulatory process needed to be science-based ("*scientific review should be a separate thing. Anything to do with the benefits, social economical implications might need to be dealt with. But let's not let it shade the debate or disrupt the debate on whether a product is actually safe or not*" GD); they also identified the need to address the societal issues within the process: "*Bringing in the socio-economic considerations; looking at the benefits this could bring for the farmers and consumers*" IC. The group made the point that the regulatory process should be operated consistently "*if products are deemed safe, they should be approved for the market to make the decision. In that respect it could be greatly improved*" (ID).

The NGO group expressed concern over the centralised approach to decision making in the EU. This was two-fold: one, in relation to the science and where it was done ("*research could be done anywhere in the EU... ...I would be worried-*

just imagine a bit of duff science from Hungary in a few years' time, completely different ecology then the UK" NB); and also, in relation to countries making their own decisions about whether GM crops can be commercially grown (*"countries need to have much more scope in relation to their own environment also their agricultural practices what they are doing"* (NC), *"you have to have national derogation, even regional derogation"* NG). The group also expressed the wish for greater transparency, seeing the Food and Feed regulations as making things more difficult *"because the access to the information is managed now by the Commission, by EFSA"* (NC). They questioned the need for EFSA, and also criticised ACRE for having closed meetings when reviewing applications (appendix four A, table 4.4). They raised the need to consider GM in the wider context of sustainability, which they perceived would improve the regulatory process: *"we do need to put GM crops in a broad frame so I don't think that it is sufficient to say ok well it doesn't do any biological harm which we can detect. Therefore it is good or ok. I don't think it should work like that"* (ND). The group also, again, expressed a lack of knowledge about the regulatory process.

The scientists group saw the regulatory process as an evolving process *"potentially any or all of it can be potentially improved. I don't ever see it as a static document."* (SD). They stressed the need to see the GM risks in the context of agriculture as a whole, that *"in most cases they don't see the effect in the variation or varieties used or even the system"* (SF). They also questioned the concerns expressed by those who felt the regulatory process was too narrow, as *"the risk assessment is always jumping through some sort of hoop"* (SA). They did raise the question about whether societal assessments should be incorporated into the regulatory process (appendix four A, table 1.5), however.

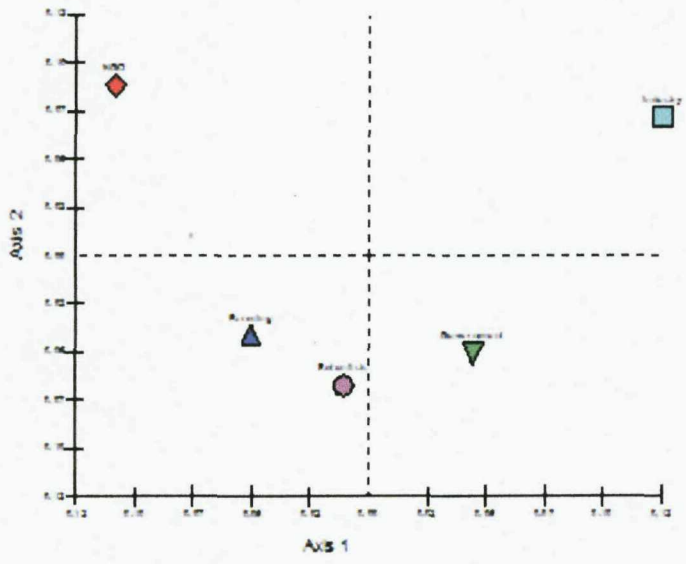
4.3.4.1 Stakeholder group comparison of themes

Only a couple of themes are mentioned across the stakeholder groups (table 4.4). The farming, NGO and scientists groups identified a lack of knowledge and the government and scientist groups saw the regulatory process as evolving.

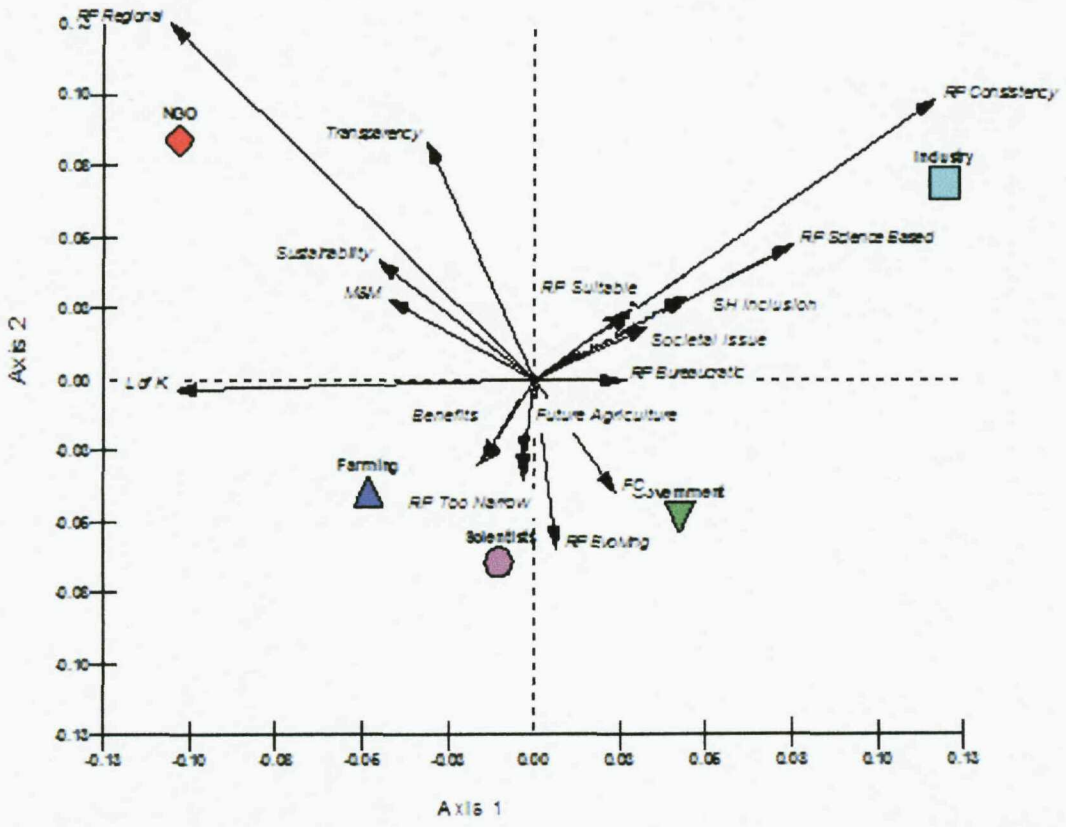
Using PCA, eighteen themes from the initial list of eighty one identified in the stakeholders response loaded either negatively or positively on to either of the two axes (appendix four B, table 4.4), representing 67.39% of the variation. In relation to axis one, both the industry group and the government score positively (the government group to a lesser extent), whereas the NGO group scored negatively, as did the farming and scientist groups (again to a lesser extent). In relation to axis two, the farming, government and scientist groups all scored negatively; with the industry and NGO groups scoring positively (figure 4.4B).

Figure 4.4: A) Stakeholder group positioning on the two PCA axes accounting for 67.39% of the variance in the responses to interview question RA2bd (improvements). B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes.

A)



B)



The government group clustered with one theme in particular (figure 4.4B); the need to consider future crops when discussing improvements to the regulatory process (appendix four A, table 4.2). They saw future crops with new or more complex combinations of traits as stretching the current regulatory process, requiring it to evolve. Two other themes: the need to consider the regulatory process as an evolving process (appendix four A, table 4.2), and that it is becoming increasingly bureaucratic, in relation to how EU laws are translated into national legislation, also contribute to explaining the government groups response (appendix four A, table 8.2).

A number of themes grouped with the NGOs: the need to consider the regulatory process on a regional level, the issues of transparency, sustainability (appendix four A, table 4.4) and management and monitoring (appendix four A, table 8.4). The group identified the need to look at the regulatory process at a regional level, as this is the only way they envisage areas remaining GM free. They also question a centralised approach to the scientific assessment (appendix four A, table 8.4). In terms of transparency, the group identified the need for more open access to the notification dossiers and the advisory body meetings. The group also specified the need to look at GM within a broader, sustainable approach. Their concerns about transparency and sustainability have been discussed in more detail above when describing the key themes (see section 4.3.4). In relation to monitoring the group felt that *"currently we do not have the mechanisms for doing that so far, I think with new agricultural technology"* (NA) (appendix four A, table 8.3). The group was diametrically opposite to the government group, which is suggestive that the views of the two in relation to the improvements needed are conflicting.

The scientists group also discussed the need to consider the regulatory process as an evolving one, when discussing improvements and that it was too narrow (appendix four A, table 4.5). The scientists and farmer groups also clustered with a group of themes including: the benefits and the need to consider the future of agriculture (In relation to the benefits both groups identified the need for their inclusion, although the scientific group go into more detail discussing the

practicalities of this (appendix four A, table 8.5). In terms of the future of agriculture, the farming group cited the need to set goals "*defined at the outset where you are trying to go with food and farming*" (FH), GM they felt could then be assessed within the context of these goals to see whether it was indeed a suitable tool for sustainable agriculture (appendix four A, table 8.1). The scientists group questioned the reductionist thinking surrounding the regulations of GM crops proposing that "*it would be better to introduce a series of measures that we know would be clearly beneficial; to make this compulsory for farmers.*" (SH). Both groups' points, in relation to the future of agriculture, relate to the need to look at GM and its regulations in relation to the wider context of agriculture and what society would like to see this achieving.

Finally the industry group clustered with a number of themes: that the regulatory process is suitable and needed to be science based, for it to include societal issues but most notably the need for regulatory consistency (appendix four A, table 4.3), see section 4.3.4.

4.4 Discussion

The stakeholders identified numerous issues in relation to the regulatory process, its scope and the review process. Not all can be covered in detail, however there are a number of overlying themes that encapsulate the numerous issues the stakeholders raised.

These overlying themes have been examined in detail (sections 4.4.1-4.4.4) and include: the differing perceptions the various stakeholder groups have of the regulatory process; the role of expert evaluation, wider society, and politics; the reasons behind the NGO group's rejection of the process; and the need for comparisons to be drawn with the regulations governing conventional agriculture.

4.4.1 Differing perceptions of the regulatory process

Clear distinctions can be made between the government and NGO groups based upon their perceptions of the regulatory process: The government group described the regulatory process as being complete, whereas the NGO group perceived it to be improving; these are two very differing views on the regulatory process. When looking at the process, it is understandable why both groups have come to such different conclusions. In recent years there have been a series of significant additions to the GM legislation, with the replacement of Directive 90/200/EEC by Directive 2001/18/EC governing the deliberate release of GM crops in 2001, the revision of the Food and Feed regulation in 2003 and the introduction of the new Traceability and Labelling (1830/2003) and Transboundary movement Regulation (1946/2003). These inclusions have certainly increased the scope of the regulatory framework and have addressed a number of concerns raised about GM crops, in relation to consumer choice (Hu et al., 2005; Miles et al., 2005), the indirect effects of GM crops (Cauley, 2001) and the issue of labelling thresholds (The Soil Association, 2006). It is therefore understandable why the government group perceived it to be "almost complete".

A good example which illustrated the differences between the government and NGO group in relation to the regulatory process is coexistence. The NGO group identified coexistence as an issue that the current regulatory process is failing to address (Friends of the Earth, 2003a; Friends of the Earth and Greenpeace, 2006). This is despite the recent inclusion of EC guidelines to develop strategies and best practice, which are aimed at ensuring the coexistence of GM crops with conventional agriculture (Council of the European Commission, 2003a), and enabling Member States to produce coexistence measures that will *"ensure an equitable balance between the interest of farmers of all production types"* (EFSA, 2003). In fact Greenpeace and other NGOs consider the new coexistence guidelines a *"disgrace, because it does not give priority to GM-free farming"* (Biosafenet, 2004). Central to their concerns are the threshold levels of acceptable GM contamination. The guidelines are based on the legal labelling thresholds and purity standards for GM food, feed and seed (EFSA, 2003). This means applying the 0.9% threshold levels, which in the view of the NGOs are not low enough. They required thresholds to be set lower, at 0.1% , as they feared that a threshold of 0.9% will make it increasingly difficult to produce uncontaminated seed. This is a concern echoed by the European Union's Scientific Committee on Plants (AEBC, 2001); however the EU Environment Committee voted against lowering the 0.9% threshold to 0.5% (Friends of the Earth, 2003a; Friends of the Earth, 2003b). NGOs also raised concerns that no solutions have been given for liability in the case of contamination, and that while the guidelines advise Member States to examine existing civil liability laws (Council of the European Commission, 2003c), in reality, in the UK certainly, it would be increasingly difficult for non-GM farmers and operators to prove who caused GM contamination (Friends of the Earth, 2003c). The non-GM farmer will need to provide evidence of GM contamination and is responsible for meeting the costs of necessary analysis (Biosafenet, 2004), this, Friends of the Earth felt, *"goes against the polluter pays principle and is therefore unacceptable"* (F of E, 2003b). The coexistence debate illustrated the divergence in views between NGOs and the government in relation to just one aspect of the GM legislative scope.

Despite identifying that the regulatory process, in general, was improving, when asked about the review process, the NGO group perceived it to be poor (figure 4.3 B). This was in stark contrast to the farming group who identified the review process as thorough and the regulatory process in general as robust. These are clearly divergent views of the review process (and to a lesser extent the regulatory process in general) which can be explained, in part, by trust. Trust is crucial when familiarity, knowledge and understanding are lacking (Earle and Cvetkovich, 1995; Earle and Cvetkovich, 1997) (Chapter One, section 1.6.7). This is not to say either group is not knowledgeable about GM, the risk and the regulatory process; however neither is explicitly involved in the regulatory decision making process or risk assessment, and therefore requires "experts" to make decisions on their behalf. For decisions based upon expert evaluation to be accepted by society, a certain level of societal trust is required in the process, the science, and those involved (Chapter One, section 1.6.7). The farmer group were confident in the ability of the current regulatory process to ensure environmental safety, and justified this by expressing the trust they had in the science underpinning the process and the science involved in it. This is essential, especially in situations whether there is a deficiency in knowledge, which the farming group identified, as then there tends to be greater reliance on trust (Earle and Cvetkovich, 1997; Peters and Slovic, 1996; Siegrist, 1999).

The NGO group, on the other hand, raised concerns about the underlying philosophies upon which the regulatory process was based and its resulting scope (section 4.4.3). They also criticised EFSA, the expert body responsible for undertaking the regulatory assessment (section 4.4.2.1), demonstrating the lack of trust the NGO groups have in the process, the science underpinning the process and those involved in it. The difference between the two groups in terms of their trust in the ability of the process to fulfil its regulatory requirement goes someway in explaining their differing perceptions of it.

The government group, like the farmers perceived the regulatory review process to be thorough; however unlike the farmer group, the government group are familiar with the regulatory process, its scope and how it is reviewed. Indeed they

gave a detailed overview of the review process in their responses. Familiarity with the regulatory process, understanding how and why a product is regulated in the way it is, means it is more likely to be accepted.

Familiarity or trust, are clearly essential in the acceptance of regulatory decisions (Cantley, 2004; Gaskell, 2004c; Poortinga and Pidgeon, 2005). Yet while trust can be substituted for familiarity, it is unlikely to work the other way around. Familiarity often presumes a certain level of knowledge and understanding; as one can only be truly familiar with something when one fully understands it. To fully understand the scientific regulatory process governing the deliberate release of GM crops requires a certain level of scientific knowledge and regulatory understanding, which few are privy too. Those lacking relative knowledge, understanding and familiarity with the process have to rely upon others to make decisions for them, and this requires trust. Trust and familiarity are therefore totally different entities. Familiarity is knowledge based and therefore quite specific to the issue in question; trust is much broader and is dependant on a number of things such as personal previous experiences, beliefs, as well as information (Cvetkovich, 1999; Kasperson et al., 1999)(see Chapter One section 1.6.7). As a result those accepting a decision based solely on trust will consider a wider range of issues than those who base their acceptance on familiarity. This has been illustrated a number of times in this study. For example when considering the differences in the groups' environmental concerns: three groups, government, industry and scientists, have had much greater involvement in the regulation of GM crops. As such they are more familiar with this and have greater scientific knowledge and understanding. When discussing their environmental concerns, they stated issues specific to the regulatory process and the science-based environmental risks assessed within it. The farmer and NGO groups on the other hand are less familiar with the regulatory process and do not in general have the levels of scientific understanding or knowledge available to the other three groups. They are therefore required to place greater emphasis on trust, when it comes to accepting regulatory decisions. They considered much broader issues when discussing their environmental concerns (Chapter Three, section 3.4.6), both groups drawing upon their wider experiences to provide a context with which they

were familiar, in order to evaluate the crops. The farmer group drew comparison with conventional agricultural production, where they identified many similarities in terms of environmental risks (Chapter Three, section 3.4.8.1) and regulatory requirements (Chapter 4, section 4.4.4). Their previous good experience with the way in which conventional agriculture has been regulated and assessed had given them no reason not to trust the GM regulatory process or those involved in it. The NGO group, on the other hand, drew upon different experiences, considering both past experiences where agricultural production has had a negative impact on the environment and also cases where science and innovation have failed (Chapter Three, section 3.4.6 & 3.4.8.3). Previous negative experiences have caused the NGO group to question why GM should be any different; poor regulations have been in part to blame, as have those involved in the regulatory process. The result of this is a loss of trust in both the regulatory process itself and those charged with implementing it.

The route forward is complicated, as trust is not easily recovered (Chapter One, section 1.6.7.6); as previously mentioned while trust can make up for a lack of familiarity, familiarity does not make up for a lack of trust. As a result, simply trying to improve acceptance of the regulatory process by increasing people's knowledge and understanding of it is unlikely to succeed. Better communication of the process may somewhat improve familiarity, however it is likely to only address the concerns of those already familiar with the process, as those whose acceptance is reliant on trust will have much broader concerns and this has previously proved to be counter productive (Fischhoff, 1995) (Chapter One section, 1.6.7.6). Trust will only be regained if it is acknowledged to be lost in the first place and then steps are taken to address the underlying concerns.

4.4.2 The roles of scientific advisory bodies and politics in the regulatory review process

The roles of both expert advisory bodies and politics were identified as a key issue by the stakeholder groups; and indeed the interplay between the two is very interesting. While it is the responsibility of the scientific advisory bodies at both

National and EU level to assess applications for release, it is the Council of Ministers (a politician from each of the Member States) who has the deciding vote as to whether an application is to be approved (Chapter One, section 1.5.1 and appendix one, table 1.4).

4.4.2.1 The competency of scientific advisory bodies

A number of the stakeholder groups discussed the competency of the advisory bodies, in particular EFSA (see sections 4.4.1-4.4.3). In particular the scope of the experts sitting on advisory bodies and the agendas of individuals involved was brought into questions (summarised in table 4.5), as well as the transparency of the process. EFSA have attempted to address all the of concerns raised by the stakeholder groups, being as open and transparent as possible without breaching commercial confidentiality requirements (EFSA, 2007a); this, however, has not seemed to quieten the critics.

Acceptance of a regulatory process and the decisions made by it often require trust (see section 4.4.1). A key component of trust is shared perceptions of risk; this is why reframing a technology to reflect the salient values of society will often increase trust (Siegrist, 2000) (Chapter One, section 1.6.7). For example, you are more likely to accept a decision made for you by someone who shares your ideals than someone who does not. The same can be applied to advisory bodies, as it is rarely those who agree with the regulatory decisions that criticise the bodies making them, at a Member State level. A lot of the criticism of EFSA stems from countries who do not agree with EFSA scientific evaluations. Certainly the countries who are considered anti-GM in their voting (see section 4.4.2.3) are often the loudest critics of EFSA, for example, Denmark, who continuously vote 'no' regarding applications for release, despite the EFSA evaluation and also "*oppose the centralisation of responsibility for the risk assessment in the negotiations about the establishment of EFSA and the Food and Feed regulations*" (Toft, 2004).

	Criticism of EFSA competency and transparency	EFSA's and the EU parliaments response to these criticisms
Scientific competency	Whether there is the scope in the EFSA GMO panel to adequately assess the environmental implications (appendix four A table 1.3, 2.2, 3.4 and 3.5). A number of EU Member States have raised similar concerns (Tiberghien and Papic, 2006).	Both the EU parliament and EFSA have defended the competency of the EFSA GMO panel and the expert selection process (Buonanno and Nugent, 2002; Council of the European Commission, 2001b; EFSA, 2007a). In addition to the 21 scientific experts who sit on the EFSA GMO panel, credentials of whom can be viewed on the EFSA website (EFSA, 2007c); there is the scope to invite Ad hoc experts to supplement the knowledge of the panel in relation to specific issues (EFSA, 2007a). EFSA also highlighted the potential, within the review process, for Member States to give scientific input into each application for release, if they deem it to pose particular threats to their specific environment (EFSA, 2007b); this should negate the concerns of particular Member States about the lack of relevant expertise to assess the threats posed to their particular region.
	Whether the EFSA GMO panel is representative of all the Member States and the various regions (appendix four A, table 3.2).	
Individual agenda	Links to industry (appendix four A, table 1.3) and EFSA GMO panel members expressing pro-GM attitudes	EFSA have taken a number of steps to address the issues associated with individual members' links with industry. They require each of the 21 GMO panel members to state their relations and any income from industry sources on the EFSA website (EFSA, 2007b). Holland (Holland, 2004) presents an interesting discussion about both the lobbyist and lobbied within the GM regulator process. In the report she too concludes that "*in principle they* [EFSA experts] *should not be open to lobbying*"(Holland, 2004); identifying that the majority of lobbying (both pro- and anti-GM) is at the European Commission, Council and Parliament level.
	Conflicts of interest with individuals sitting on both National and EU advisory bodies.	Where potentially conflict of interest issues relating to certain experts sitting on both National and EU advisory bodies, a point highlighted in both Greenpeace and Friends of the Earth reports (Friends of the Earth, 2004; Greenpeace, 2005). EFSA supports the use of experts on their GMO panel who also sit on National advisory bodies; they see this as "intellectual interest" and a way of ensuring relevant expertise, as "*relevant expertise is dependant on prior expertise*" (Friends of the Earth, 2004). However the NGOs counter this by the question that if it is purely intellectual interest rather then a conflict of interest, why do experts need to abstain from the EFSA decision making process if they have cast votes on a particular application at a National level and is focused on swaying political votes and opinions?
Transparency	The NGO group (appendix four A, table 3.4) and literature (Greenpeace, 2005; John, 2006) both criticise the transparency and openness of the EFSA deliberations. Requiring greater ease of access to application dossiers.	The criticisms of EFSA in regard to transparency mirror those lodged at ACRE and other National expert bodies. Transparency is acknowledged as "*an important factor in maintaining a system which commands the confidence of the public.*" (House of Commons, 1999) however, it is acknowledged that this should not come at the cost of commercial confidentiality. Commercial confidentiality is a contentious topic, the Consumer Association felt it "*can be used as an excuse to prevent the disclosure of information*" (House of Commons, 1999). Currently, UK government support the need for advisory bodies like ACRE to have closed meetings, where transparency should "*be a presumption in favour of public disclosure unless applicants can demonstrate that disclosure would cause commercial harm*" (House of Commons, 1999); a stance taken by EFSA (EFSA, 2007a) but criticised by NGOs

		(Greenpeace, 2005).

Table 4.5: The criticisms relating to EFSAs competency and transparency made in the literature from various sources; alongside the responses from EFSA and the EU addressing these criticisms.

The centralisation of EFSA in the assessment of applications is a particular concern of the NGO group, who stressed the need to regulate GM on a National, if not regional level (see section 4.4.3). This is a campaigning standpoint taken by a number of NGOs (Friends of the Earth, 2007) who have jointly started the campaign "GMO-free regions for a GM free Europe" (GeneWatch and Greenpeace, 2007a). The campaign allows regions and municipalities to declare themselves and their food producers GMO free; so far 174 regions and over 4500 municipalities have done so. They have also held a number of conferences focusing on the devolution of centralised GM legislation (Etty, 2007), highlighting the importance of regional devolution to NGOs. As well as the implications centralised regulations and scientific reviews can have on the ability for Member States or regions to remain GM free, the NGO group also highlight the implications it could have on research in general. They feared that *"research could be done anywhere in the world"* (NB appendix four A table 2.4) which might have ecological implications due to spatial environmental differences. The decentralisation approach to regulations, however, is seen by some as a way for NGOs to disrupt the harmonisation of the regulatory approach in Europe; indeed the group themselves acknowledged this, stating *"industry would hate it, they would say it is just putting unnecessary obstacles in the way in the UK, it has been tested in the EU so just get over it"* (NB appendix four A, table 2.4).

There are no easy solutions to the lack of confidence some stakeholder groups and even EU Member States have in EFSA competency to undertake the scientific evaluations of applications for release. EFSA needs to continue to address the concerns raised and improve the transparency of the process to ensure that all decisions are fully justifiable. An open review of the EFSA expertise might go some way to addressing the criticisms made; however there will always be those who disagree with the decisions made by EFSA and therefore will question their competency.

4.4.2.2 *The role of wider society and the inclusion of their concerns*

The government, industry and scientists groups all discussed the inclusion of societal concerns into the regulatory process; and in the case of the government group, the role of laypeople representing society on advisory committees such as ACRE. The industry group called for the process to be an independent science-based review of safety which is not marred by the politics (see section 4.4.2.3). They acknowledge "*the benefits, social economical implications might need to be dealt with*" (IB), reiterating the need to consider "*looking at the benefits this* [GM] *could bring for farmers and consumers*" (IC) (appendix four A, table 4.3). The scientist group also identified the need to consider societal factors in recognising that this "*would be a way forward... to broaden it from the science based risk assessment*" (SI) (appendix four A, table 4.5). It is clear that a proportion of society, which includes some scientists, NGOs, farmers, members of government, and the public in general, does have socio-economic concerns in relation to the deliberate release of GM crops and feel it to be the responsibility of the regulatory process to address these. Some in the science community suggest "*the integration of public concerns into policy development and implementation, will facilitate the introduction of emerging technologies and their applications into society*" (Frewer et al., 2004); but see it as "*one of the biggest challenges facing those who want to see safe, equitable, and locally appropriate development of new biotechnologies*" (McAfee, 2004) (Chapter One, section 1.6.8). There is very little in the scientific literature which proposes a way that this should be done. Stirling and Mayer discuss the use of multi-criteria mapping as an alternation to the current regulatory process (Stirling and Mayer, 2001), and ACRE propose the use of Comparative Sustainability Assessments (CSA) as a way of incorporating a benefit assessment in to the current process (ACRE, 2007a) however this is clearly an area where more scientific deliberation is required. In the recently published DEFRA project AR0317, they too consider ways in which the benefits can be considered in relation to the risks and support the findings of the ACRE report (Pidgeon et al., 2007).

The government group also expressed the need to include social issues in the regulatory assessment. While they deemed social issues important and in need of addressing (appendix four A, table 3.2), the group did not feel that this should be done within the evidence-based risk assessment; this they felt should remain based purely on the science. The group also discussed the inclusion of the laypeople on the advisory bodies. Their view was that advisory bodies require "*independent scientists to look at the science and evaluate the risks*" (GD); and therefore there is not a necessity to have societal representation on advisory bodies such as ACRE, indeed it could prove detrimental. The view of the NGO group deviated greatly from the government group's stance, they felt there needed to be "*a much greater openness to the sorts of people doing the regulating* [in EFSA], *non-scientists non-expert consumer representatives, involved in the process*" (NF) (appendix four A, table 3.4). In a joint report by environment, consumer and health NGOs (Greenpeace, 2005) they called for the "*Stakeholder Platform to be open, transparent and functional. We believe the EFSA should allow stakeholders to have at least two representatives*" on the panel; they also felt that "*All stakeholders should be able to write directly to scientific panels. In the name of transparency the EFSA should publish all correspondence on their website*". This need for a stakeholder 'regulated' review of the EFSA assessment process reiterates the lack of trust NGOs have in EFSA to deliver an unbiased opinion (see section 4.4.2.1), a point made in the NGO literature (Friends of the Earth, 2004; Greenpeace, 2005; Levidow et al., 2005). The government group, however, felt that Ministers represent the concerns of society at the decision making level and have "*indeed overruled ACRE on a number of issues; if there are societal issues they fell important, then they will take that into consideration.*" (GE); it is at this level societal concerns are, and should be, addressed.

In the UK, the government has always attempted to keep the social issues separate to the scientific evaluation. The Agriculture and Environment Biotechnology Commission (AEBC) was established in June 2000 as a strategic commission containing a "*range of experts covering scientific issues as well as, for example, ethics and consumer issues*" (Office of Science and Technology, 1999) at a time when public controversy surrounding GM crops was at its height and there was a

desire to understand why the existing scientific advisory process appeared to lack authority with the public, (Williams, 2004). Its establishment followed a review by the Cabinet Office and the Office of Science and Technology (Office of Science and Technology, 1999), which identified a number of weakness with the current advisory system; setting up the AEBC "*as part of a new framework to address these weaknesses and increase public understanding of and trust in the ways in which the advisory structure engages with and addresses public concerns over biotechnology*" (Williams, 2004). Although the AEBC was disbanded in 2005 after an independent review (Williams, 2004) resulted in the government concluding that "*the commission had largely discharged its original remit*" (DTI and DEFRA, 2005), it was felt that the AEBC had made "*a significant contribution* [to the GM debate in the UK] *over the last five years*" (DTI et al 2005); the most notable contribution of the AEBC being the instigation of the 'GM Nation? The Public Debate' in 2003 which arose out of an AEBC recommendation to the government (DTI, 2003; Williams, 2004). The formation of the AEBC exemplifies the government's willingness to consider wider social issues, but for these issues to be removed from the scientific assessment of the crops undertaken by ACRE. Its disbandment in 2005 was due more to role framing issues (DTI and DEFRA, 2005; Williams, 2004), then any acknowledgement by the government that identifying and addressing the wider social issues were no longer necessary. The government now believe "*existing bodies can between them take forward the AEBC legacy*" (DTI and DEFRA, 2005) singling out the Centre of Excellence in Science and Technology Horizon Scanning as the body who could work with stakeholders in identifying issues which require wider consideration.

4.4.2.3 Concerns about the influence of politics

While the EFSA undertake the scientific evaluation of applications, it is a Council of Ministers (one from each Member State) who vote on whether they are to be approved or not. This is a particular sticking point for the industry group, who perceived the regulatory review to be inconsistent in its approach because of the voting of Member States. This inconsistency is amplified with the introduction of the Food and Feed Regulation, which meant applications for release can be

submitted through two routes (via Directive 2001/18/EC or the Food and Feed Regulations 1829/2003). The importance of this becomes clear when considering the composition of the Council of Ministers voting on the applications. For example, in Ireland, Directive 2001/18 is voted on by the Environment Minister who often votes negatively; where as the Food and Feed regulation is covered by the Agriculture and Health Minister, who often votes positively (Little, 2006). These regulatory inconsistencies, borne out of politics, are not only frustrating for industry but also for other stakeholders, who deem that the scientific review should be the basis for the voting, as stipulated in the regulations (Council of the European Commission, 2001b; Council of the European Commission, 2003b), not the political orientation of the Minister or Ministry in charge. Political rather the scientific voting is particularly apparent when considering the way certain Member States vote, as there is a certain pattern to the way countries vote on GM applications. Post-moratorium (December 2003) there have been 18 votes all of which have failed to reach a qualified majority: Each time the Czech Republic, Finland, the Netherlands, Sweden and the UK systematically vote in favour (following the guidance of EFSA), while Austria, Cyprus, Demark, Greece, Italy, Lithuania, Luxemburg and Malta systematically vote no; interestingly Spain and Germany almost always systematically abstain from voting (Tiberghien and Papic, 2006). The concerns are that not only does political voting detract from the initial scientific remit, to assess and decide upon the scientific safety of an application, it also adds to public confusion about safety; as political voting often results in non-qualified majorities, the result of which is that the decisions are referred back to the European Commission (EC). The EC base their decisions on the scientific evaluations of EFSA, which often contradicts the Member States who have voted on a political basis. It can then look like the EC are overruling scientific concerns about risks, when they are really overruling political ones; this then has the potential to bring the regulatory decision into question.

Political voting however could be seen as a way of allowing the markets to decide upon whether GM crops are socially acceptable, as Ministers votes should be representative of their constituents. Allowing the market to judge the social and economic acceptability of GM crops, was a point argued by a number of the

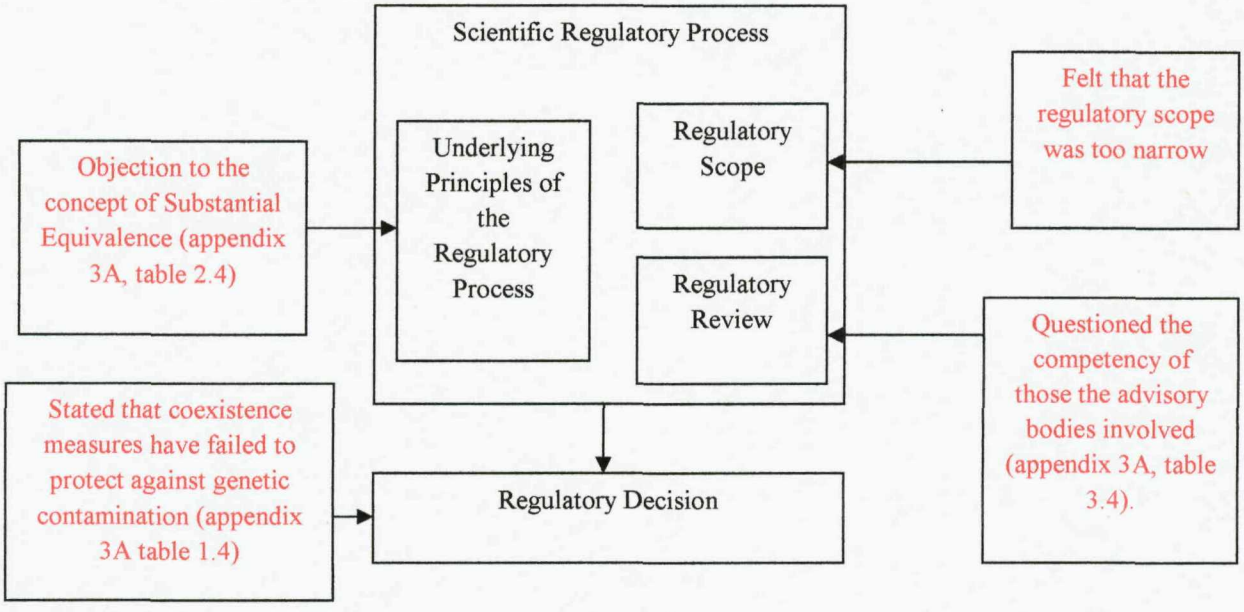
stakeholder groups (appendix four A, tables 4.5.3). As the government stakeholder group noted (appendix four, table 4.1.2), the role of Ministers in the decision making process is to represent the views of society (see section 4.4.2.2). By voting in a way that represented their countries' concerns surely the Ministers and Member States are representing their voters, as it would be doubtful that an Austrian Minister would continually vote no for any GM release if the Austrian people wanted it.

There seems to be confusion as to how much of a role science should have: should it be the sole point of reference, only focusing on the potential safety risks? Should wider societal issues such as the benefits or the ethical and economic implications be included? If so, then to what extent should politicians be representing these concerns and how should, or even could, they be measured in relation to the scientific risk assessment? These issues will be discussed in more depth in the general discussion (Chapter Six and the paper Johnson et al., 2007) as it has become a central theme to come out of this research.

4.4.3 The NGO groups rejection of the regulatory decisions and the process in general

Across all four research questions, the NGO group raised numerous concerns pertaining not just to the regulatory scope and the review process, but also criticising the regulatory decisions and the underlying regulatory philosophies (figure 4.5). Their concerns over the competency of EFSA were discussed in section 4.4.2.1.

Figure 4.5: The issues raised by the NGO group in relation to the regulatory: scope, review process, underlying philosophies and decisions made based up on it.



The NGO group used coexistence issues to illustrate the failings of the regulatory process to safeguard against environmental harm (section 4.4.1). Indeed contamination is a major issue for NGOs, with GeneWatch and Greenpeace having launched a joint collaboration tracking contamination incidents at every stage of the development process "*from lab, to field, to fork*" (GeneWatch and Greenpeace, 2007b). In total they have identified 113 incidents of genetic contamination resulting from 88 separate incidents affecting 39 countries (GeneWatch and Greenpeace, 2007b). Their concern is that current GM coexistence legislation neglects biological reality and therefore is impossible to implement (Contiero, 2007); it therefore "*protects the interests of the biotechnology industry rather than organic food producers*" (GeneWatch, 2003a).

Acceptance of a regulatory decision or process is more likely if those making the decision or in charge of the process share similar ideals (section 4.4.1). The disparity between the NGOs and regulators as to what coexistence threshold

values are deemed to be acceptable is likely to affect the NGO groups' acceptance of the regulatory decision and the process in general.

The same can be applied to the NGO's and regulator's contrasting views in relation to the appropriateness of Substantial Equivalence; an underlying regulatory philosophy. The NGO group stressed their concerns about the grounding of the regulatory philosophies, in Europe, on Substantial Equivalence. The group saw Substantial Equivalence as "*fraudulent, it is a political construct not a scientific one*" (NF appendix four A table 3.4), which violates the Precautionary approach they champion. Central to the concerns raised by the NGOs is the view that Substantial Equivalence is "*unscientific and arbitrary, encapsulating a dangerously permissive attitude towards producers, and at the same time it offers less than minimalist protection for the consumers and biodiversity, because it is designed to be flexible, malleable, and as open to interpretation as possible*" (Ho and Steinbrecher, 1998), the reason for this concern as stated on the GeneWatch website (GeneWatch and Greenpeace, 2007a): "*Substantial Equivalence is the concept behind all the GM food safety testing worldwide. If the chemical composition of the GM food is shown to be generally the same as the non-GM equivalent, it is deemed 'substantially equivalent' and therefore safe. However, there is no defined list of what has to be measured and the system does not look for unintended effects, one of the major concerns that scientists have about GM food safety*".

Despite the concerns raised by NGOs about the use of Substantial Equivalence, EFSA still maintain a central role for it within the regulatory process (Kuiper, 2006). This divergence of views between EFSA and NGOs in relation to one of the fundamental principles of the regulatory process, in part, explains the mistrust NGOs have in both the European regulatory process (see section 4.4.1) and in EFSA's competency to review applications under it (see section 4.4.2.1). It also explains why the NGOs have been highly critical of the regulatory scope (Friends of the Earth, 2004); no doubt their vocal criticisms have played their part in how the regulatory process has evolved, especially in recent years with the inclusion of

general surveillance, traceability, liability regulations and coexistence guidelines (Council of the European Commission, 2004b). These new regulations have undoubtedly broadened the regulatory scope, as have the revision of both the Food and Feed regulations and the Directive 2001/18 (Council of the European Commission, 2001b; Council of the European Commission, 2003b). They all, however, build on the same regulatory foundations of Substantial Equivalence, Familiarity and the Precautionary Principle. As the NGO group expressed their fundamental objection to Substantial Equivalence, seeing it as contravening the Precautionary Principle it is doubtful that these improvements in regulatory scope will appease NGO concerns.

4.4.4 The need for comparisons to be drawn with the regulations governing conventional agriculture

While the NGO group raised concerns about treating GM crops as Substantially Equivalent to their conventional counterparts, the farming and scientists groups stressed the need for greater consideration of GM crops in relation to these counterparts. These are obviously very different views, about how GM crops compare to their unmodified comparators. Indeed, NGOs have raised numerous concerns about the process of GM, seeing this as unique and posing many exclusive environmental (and other) risks; summarised in a report by EcoNexus (Wilson et al., 2004). The scientists and farming groups saw the potential risks GM poses as similar to those posed by conventional practices and indeed a number of scientific studies would agree that, with certain traits such as herbicide tolerance, which can be produced through GM and non-GM paths, the environmental implications are indeed similar (Dale et al., 2002; Senior and Dale, 2002) (see Chapter Three, section 3.4.1). The difference in the two groups' views seems to hinge on whether crops that have been genetically modified should be considered as 'unique', 'novel' because of the process in which new traits have been inserted. The NGO group see GM crops as being novel due to their production methods and therefore needing to be thoroughly assessed independently of whether they are deemed Substantially Equivalent to their conventional counterpart, or not; and the scientist and farming groups seemingly judge the novelty of the GM crops on the traits they possess rather then the

production methods, and therefore draw comparisons with GM and non-GM crops that possess the same traits. The difference in views between these stakeholder groups seems to be an extension of the "product/process" debate which separates the European regulatory approach from that of the US or Canada (Nap et al., 2003). Neither the NGO or scientist/farmer groups concerns are really represented by the current EU regulation, which deems GM to be novel thus requiring regulatory assessment (Council of the European Commission, 2001b) unlike conventionally bred varieties, but then use Substantial Equivalence as a measure of the extent to which regulatory assessment is required.

In fact, all the groups identified the need to consider the regulation of GM within the context of what is applied to other conventional methods of agricultural production. Conventional agriculture was perceived as relatively under regulated in comparison to GM. When discussing the regulatory scope, the government, industry and scientists groups compared the regulatory requirements for both GM and non-GM crops, they felt the regulatory process was "*preoccupied with one process of crop improvement to the exclusion of other methods of plant breeding*" (SH appendix four A, table 1.5). At a regulatory level, with the release of the ACRE report (2007a) the imbalance in regulatory assessment is beginning to gain attention. The ACRE report identifies the need to examine "*other novel crops and agricultural processes... as it has become apparent that there are inconsistencies in the regulatory assessment of the environmental impact of GM crops in comparison with other crops or practices*" (ACRE, 2007a). It will be interesting to see the official responses to the report, both at the regulatory level within the EU and UK (as well as other Member States) and also in terms of the responses coming from the stakeholder groups. The need to draw comparisons between GM crops and other forms of agricultural production has been a central theme identified by the stakeholder groups in relation to all three research aims and thus will be discussed at greater lengths in the general discussion (Chapter Six).

The farmers and scientists groups went further than simply requiring comparison to be drawn; they stipulated the need to identify future goals for agriculture within

the context of which GM crops could be evaluated (appendix four A, table 8.1 and 8.5), when discussing improvements to the regulatory process. The scientist group went on to identify this as a potential management goal (Chapter Five, section 5.4.5). By considering GM in relation to these broader agricultural goals, the environmental implications for GM adoption can be contextualised. Evaluating the environmental implications requires the assessment of the potential benefits as much as it does the potential risks. Consideration of benefits was something the farmer group deemed to be important (Chapter Three, section 3.4.3). The way in which GM can be regulated within the context of future agricultural goals is discussed in Chapter Six. The NGO group also identified the need to consider GM crops in a wider context. They stipulated sustainability should be the goal for agriculture in general, and as such should be the driver for GM regulations. This is unsurprising as sustainability is a big issue across the board for many of the environmental NGOs; whether it is in relation to agricultural, or the utilization of any global resource (Hemmati, 2002; Pouteau, 2000). All three groups identified the need to place GM in this wider context of where they envisage agriculture should be heading. Clearly there are marked differences between the scientist/farmer groups' requirement of setting future agricultural goals, and the NGO group's more direct target of sustainable agriculture; however it does illustrate the desire of a number of groups to consider GM and agriculture in a more holistic and directed fashion (see Chapter Six).

4.5 Conclusion

Three points in particular encapsulate the concerns of the stakeholder groups in relation to the regulatory process; they also illustrate how the views of the different group vary, in some cases dramatically. These three points are: the suitability of the current process; the need for the current process to be considered within the context of what is required for current conventional practices and the environmental risks these poses; and the roles scientific risk assessment, societal concerns, and political decision making should have.

4.5.1 The suitability of the current regulatory process

In relation to the suitability of the regulatory process, there is generally divergence in the stakeholders' opinions, which reflects the concerns they raised. Trust and familiarity have been demonstrated to be important in the acceptance of the regulatory decisions and the regulatory process in general. There are, however, huge variations in the issues considered by those reliant on trust when ascertaining the acceptance of the regulatory process. For example, the farmer group who identified their interest in the regulatory process and those involved, drew conclusion about both the regulatory process and the environmental risks based on previous experiences with agricultural regulations and practices in general; thus considering the GM regulatory process within a broad context of previous personal experience. The government, industry and scientist groups, who are more familiar with the regulatory process, consider much more specific issues relating to the particular regulatory requirements when judging the acceptability of the process. By understanding the differences between those who rely on familiarity and those who require trust to gauge whether a regulatory process, or indeed a scientific innovation, is acceptable, will help to explain why some of the amendments to the regulatory process have appeased some stakeholder concerns but not others (see Chapter Six).

4.5.2 The need to draw comparisons with the regulations governing current conventional practices

The need for comparisons to be drawn with conventional practices was also something highlighted when considering the stakeholders environmental concerns (Chapter Three, section 3.5.2). The need to consider the regulatory requirement of GM crops within the context of those applied to conventional agricultural practices, is therefore unsurprising. There is a imbalance in the regulatory requirements governing GM and non-GM forms of agriculture and this is beginning to be recognised (ACRE, 2007a). The question remains, as to how can this be addressed? A 'levelling of the playing field' would require either a reduction in the regulatory requirements for GM or a tightening the regulation of conventional agriculture; both of which would receive opposition and criticism. Perhaps a more holistic consideration of agriculture is what is required; the

formation of clear agriculture goals, and objectives (endpoints), within the context of which GM crops and conventional agricultural practices can be evaluated (discussed in more detail in Chapter Five section 5.4.5). By doing this, some comparisons between the two can be made, in terms of both the potential risks but also the benefits. This is clearly a key issue and will be considered in more detail in the general discussion (Chapter Six).

4.5.3 The roles of scientific risk assessment, societal concern and political decision making

There is a concern amongst all the stakeholder groups' as to the interplay between scientific risk assessment and societal concern. Many raised concerns about the need to include societal issues, which might fall outside conventional scientific risks, and the extent to which the scientific assessment was taking into consideration in the political voting. The fundamental question being, what weight should the scientific assessment of risk be given in the decision about the acceptability of commercial cultivation; see Johnson et al., (2007). Currently, the risk assessment is solely scientific, and if a qualified political majority, in either direction, cannot be achieved then it is the scientific assessment made by EFSA upon which the European Council base their decision (Chapter One, section 1.4.1). This has come under criticism by the stakeholder groups' for several reasons, relating to the competency of EFSA to make the scientific decision, the issues with Member States voting politically rather then on the science, and the lack of an explicit inclusion of societal concerns. The need to clarify the extent of the role science should have in the regulatory decision to approve GM crops has become one of the central issues to come from this study, and as such will be addressed further in the general discussion (Chapter Six)

Chapter Five

Management goals and assessment endpoints identified by the Stakeholders

5 Chapter Five: The stakeholders proposed Management Goals and Assessment Endpoints

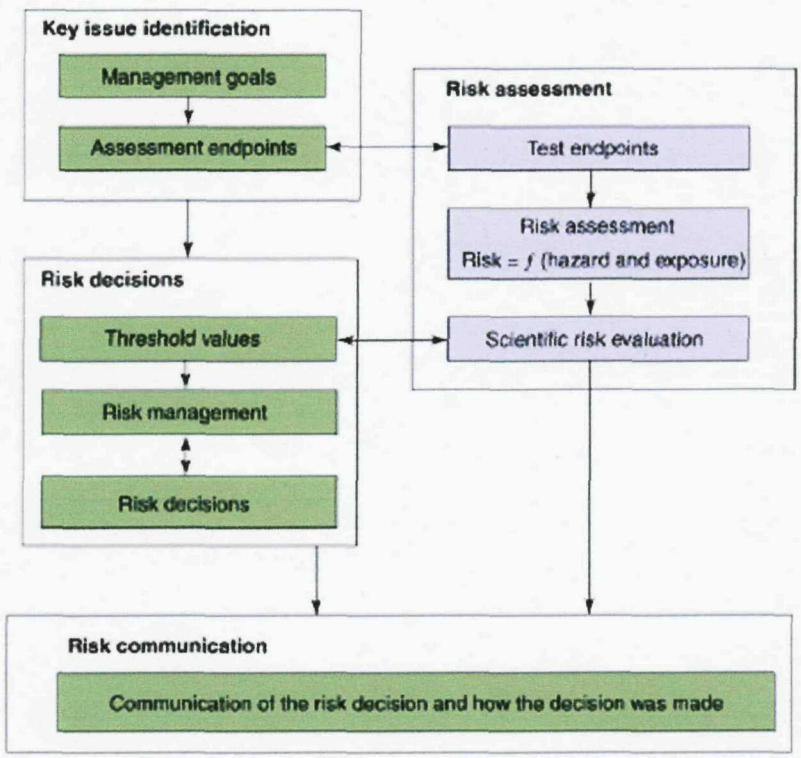
5.1 Introduction

The European regulatory system is considered by many to be the most stringent in the world (Nap et al., 2003; Schilter and Constable, 2002); however it has not succeeded in dispelling concerns over the safety, in particular environmental safety, of GM crops. The independence and appropriateness of the process, its scope, and the validity of the science that assesses the risks, have all been brought into question (Levidow and Carr, 2000b; Lonnroth, 2003; Sjoberg, 2001) (Chapter One, section 1.6). Most of the solutions to these criticisms, given by opponents of the current regulatory process, are focused on the scientific risk assessment. They stressed the need to broaden the regulatory scope, so that it would include ethical and economic concerns as well as safety aspects, and also the need for widening the expert panels to include non-experts and for their meetings to be more open (Krayer von Krauss et al., 2004; Sjoberg, 2001; Wallis et al., 2005).

The concerns raised are valid; however they are not legitimate criticisms of the risk assessment. What often is not acknowledged, or even understood, is that the "*scientific risk assessment is just one part of a larger evaluation of the desirability of permitting the cultivation of GM crops, or any other activity judged to raise potential risks*" (Johnson et al., 2007). This wider evaluation is risk analysis, and it is within the risk analysis rather then the risk assessment where societal concerns can be addressed. Risk analysis consists of various components (figure 5.1), one of which is the risk assessment. The risk assessment however is purely the scientific tool used to quantify the risks; it is neither the driver of the analysis nor the sole component of the risk decision (Suter, 1989). Management goals (MG) should be the drivers of the risk analysis, and thus the risk assessment; these should be reflective of societal concerns and are often specified in legislative policy (Johnson et al., 2007). Assessment endpoints (AE) can then be generated from these MG and are therefore also driven from what society deems important. AE can be used to identify a series of objectives, which have increased, focused

rigour and achievability, but are still representative of the original goals. Test endpoints can be derived from the AE and are achievable, testable, auditable targets; representative, again, of the initial goals however quantifiable. It is these test endpoints that the risk assessment aims to achieve. The risk assessment then informs the decision making process, it does not dictate it; "*a decision will be made based on the amount of risk that is acceptable (threshold value) if the crop is permitted to be cultivated and just as importantly, the risks of not permitting cultivation*" (Johnson et al., 2007).

Figure 5.1: Risk Analysis taken from (Johnson et al., 2007). The diagram depicts the four stages of the risk analysis; key issue identification, risk assessment, risk decision making and risk communication. Boxes highlighted in green are stages driven by society and those highlighted in purple are driven by science. Progression through the system is not linear but iterative. Feedback loops, although not included in this diagram, are an integral part of the risk evaluation.



Stakeholders need to be made more aware that risk assessment is just one part of a wider analysis of risk; and it is this risk analysis which is "*used to make decision and that reflects the rationale of non-scientific concerns*" (Johnson et al., 2007). This study aimed to explore the scientific and non-scientific concerns of the stakeholder groups; by investigating the MG and AE different groups required, through use of semi-structured qualitative interviews. By gauging various

stakeholder views in relation to MG or AE, an evaluation of the issues posed can be made. Stakeholder groups were also compared in terms of the similarities and differences in their responses. Identifying the similarities between the stakeholders' responses represents areas of mutual goals, which can then be focused upon. By also identifying how the groups differ in their views toward MG or AE, it will highlight issues which need to be addressed in order to increase stakeholder confidence in the process. The research aims are the same as in the previous research chapter (Chapter Three, section 3.1).

5.2 Methodology

The methodological approach has been set out in Chapter Two, (sections 2.2.4-2.4.3). This chapter investigated the stakeholders group's responses to research question:

RA3a: "*Are there any additional management goals or assessment endpoints which you would like to see addressing any of the issues/ concerns you have raised?*"; from this point on known as RA3a (MG & AE).

5.3 Results

The results section starts initially with the identification of the key themes for each individual stakeholder group and then goes on to draw comparisons between the stakeholder groups in terms of the similarities and differences between their responses.

5.3.1 RA3a "Are there any management goals or assessment endpoints which you would like to see addressing any of the issues or concerns which you have raised previously?" (MG and AE)

Table 5.1: Summary of the key themes identified by each stakeholder group in response to RA3a (MG and AE). SIssue= specific issue; L of K= lack of knowledge; B/D= biodiversity; Imp= Implications; Pol= political; M & M= management and monitoring; Agri= Agriculture; Comp= comparison; Chem= Chemical; RA= risk assessment.

	Farmer	Government	Industry	NGO	Scientists
Number of themes identified					
Key Themes and "proportional occurrence" scores	Benefits 2.071	Benefits 0.209	Pol Role 0.760	Market Imp 0.21	Benefits 0.544
	Wildlife SIssue 0.115	B/D Imp 0.143	M & M 0.2	M & M 0.143	Future Agri 0.204
	Contamination SIssue 0.106	GM Trialling 0.136		Threshold 0.119	Comp Chem RA 0.111
	L of K 0.1			Agri Issue 0.117	

Benefits, was a theme which came up above all others in the farming group's response to potential management goals (table 5.1). Their view was that current GM crops, such as the HT varieties, presented the least exciting potential benefits for both agriculture and consumers (appendix 5A table 1.1). The group felt that "*everyone has sort of homed in on the risks and has blinkered themselves to the benefits*" (FC); as a result of which, "*in Europe at least, this has slowed the development of other traits*" (FI). The farming group would like to see more being made of the potential benefits which could arise from commercialisation of GM crops; identifying areas where hey could be advantageous for agriculture and the consumers. With the GM crops currently available, the group felt "*the sophistication of agriculture is fairly limited*" (FI); however, these varieties of GM crops do have the potential to enable farmers to grow more crops on less land

(FD & FG appendix x table 1.1), which would be beneficial for the environment and for the farmer in terms of achieving the environmental and production targets set. When it comes to consumers seeing the benefits, the farmer group felt that future crops with improved nutrition content were potentially the way forward (FI & FJ appendix 5A table 1.1). The group did raise concerns about the potential effects GM crops could have on wildlife and the potential for GM contamination (*"you are never going to be entirely happy that you have avoided some form of GM contamination"* FB). In relation to contamination they felt that *"the contamination of other crops I don't think is a real problem"* (FD); but they did raise the need to consider the wild relatives (appendix 5A table 1.1). The group stated the need to for wildlife effects and contamination to be addressed; but also expressed concerns about how this could be achieved *"how you could actually put this into practice is again very difficult"* (FB). The group also cited their lack of knowledge when asked about management goals and assessment endpoints in relation to GM crops, (appendix 5A table 1.1).

The government group like the farmers also highlighted benefits as a potential MG or AE. They too saw future crops providing benefits for the consumer *"which maybe of more interest to the consumer because they may contain health and beneficial compounds"* (GG). The group queried the lack of a benefit assessment in the current regulatory process, stating *"several commentators... say that somehow the assessment has to look at the benefits too; because all our actions... involve in engaging in some risks and some benefits. Nothing is value neutral or risk neutral."* (GD). The group stated their concerns about the potential impacts GM crops could have on biodiversity in terms of gene flow (appendix 5A table 1.2). They advocated the need for more large-scale trialling prior to commercialisation, seeing the need for *"a middle step between the field trials and the full commercial use"* (GF); and suggesting partial commercialisation through the use of GM free zones as a way of doing this (appendix 5A table 1.2).

The industry group identified the need to address the role of politics in the regulatory (appendix 5A table 1.3). They were concerned that *"there are clear*

examples of where the systems hasn't worked and has been beset by political influence... countries' competent authorities have voted and approved an application and then the country votes against it." (IA). While the group sympathised that *"there aren't too many votes in being pro-GM"* (IE) they criticised the way certain Member States have *"formed blocking majorities in the voting system"* IA and use *"trade issues"* (IC) as a way of justifying this. The group did however praise the comatology process which gives the Commission the power to approve releases which Member States have blocked through not coming to a qualified majority vote. The industry group also discussed the process of general surveillance in relation to the endpoints which should be measured. They discussed whether the preservation of biodiversity or function should be considered important and made strong arguments for the use of functional endpoints as indicators of risk (IB appendix 5A table 1.3).

The NGO group discussed how public perception of GM has *"meant there just was no market for it* [GM]*"* (ND). The group felt that *"as long as government and the regulatory process which serves government allows people as citizens and consumers and the market which serves citizens and consumers to operate in an unfettered way the regulatory process will remain irrelevant"* (NF). Their concern was that the government might subsidise GM which would rig the market in favour of GM, as long as this did not occur the group felt that consumers will choose against buying GM production. They were also concerned that trialling GM in Europe and the UK might *"make it impossible for you to make a non-GM meal"* (NF). The group also discussed the need to assess the wide-scale implication *"of any new agricultural technology"* (NA), however they did identify that the only way to do this would be to introduce the technology. For this to happen they wanted to know that steps had been taken to assess all the potential risks and that the impacts would be monitored and plans were in place to *"pull back if they turn out to be deleterious"* (NA). The threshold level 0.9% was also discussed by the NGO group who reiterated their view that this was too high and a level of 0.1 was a more appropriate goal. The group also discussed the implications of intensive agriculture on biodiversity (appendix 5A table 1.1) and how this was having *"masses of negative environmental consequences"* (NG).

They felt that "*agriculture, farming policy and farming practice reduce* [wildlife] *those things*" (NB); and that while the changes in the Common Agricultural Policy was starting to correct this, new agricultural practices and crops should be introduced to reduce the impacts of agriculture, not to further continue them.

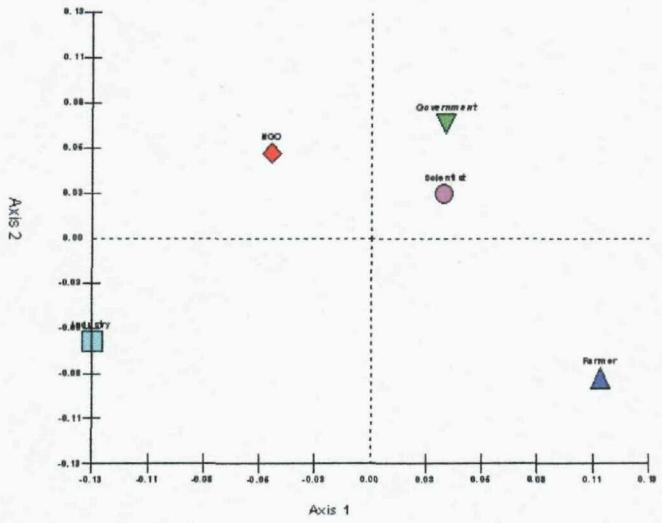
The scientists group, like the government, called for the inclusion of the benefits within the regulatory process, "*the regulations are preoccupied with risk and there is no facility within the European regulations to consider the benefits*" (SH). They identified the potential "*scientific benefits, societal benefits, stakeholder benefits*" (SE) and felt "*more weight*" (SF) needed to be placed upon these. The group also discussed the way society was more tolerant of medical applications of GM and linked that to the clear societal benefits of these applications (appendix 5A table 1.5); and the fact "*people are more indulgent toward medical companies then they are to Monsanto*" (SA). The group also discusses the need to consider what we want from agriculture; as "*there is a lot of confusion there*" (SC). Once this has been done then GM crops can be assessed within this framework (appendix 5A table 1.5). They questioned the philosophy of extensive low input farming, instead arguing a better option would be to "*increase yields on the same footprint of land and leave any new land to create and maintain biodiversity*" (SC). They also discussed the need to integrate GM risk assessment with the assessments used in other fields, as there is a lot of potential to learn from the work done there. One example given was the use of "*aggregated endpoints*" (SG) used in chemical risk assessment.

5.3.2 Stakeholder group comparison of themes

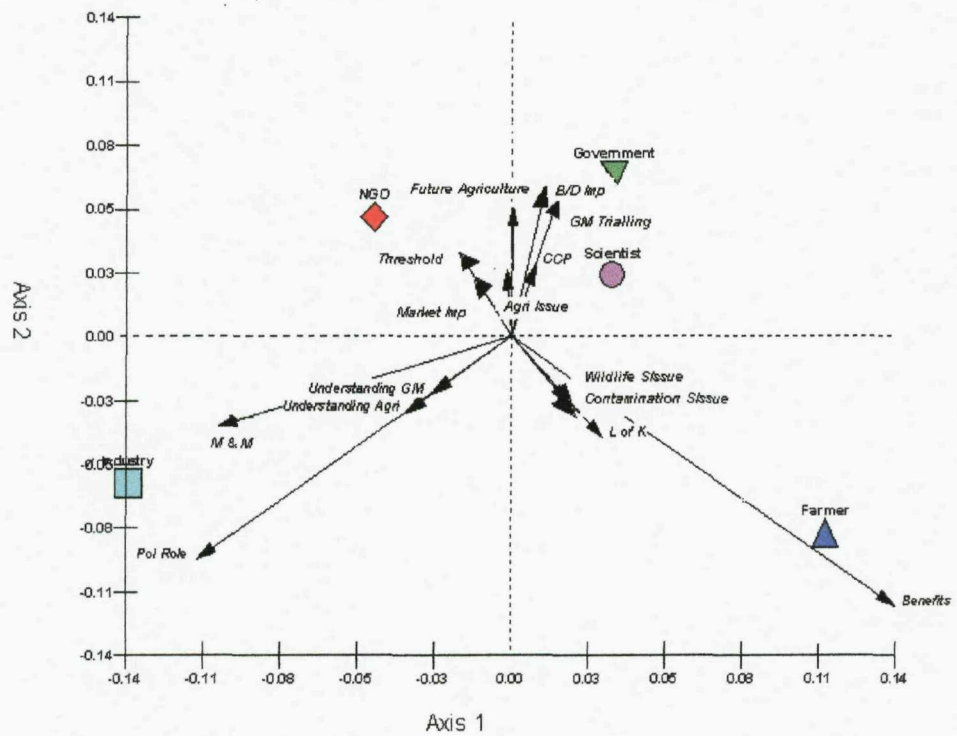
Only a couple of themes are mentioned across the stakeholder groups (table 5.1). The farmer, government and scientists groups all mentioned the benefits of GM crops in relation to potential management goals or assessment endpoints and interestingly for all of the groups benefits got the highest "proportional occurrence" score. Both the industry and NGO groups mentioned the management and monitoring of GM crops.

Figure 5.2: A) Stakeholder group positioning on the two PCA axes accounting for 71.08% of the variance in the responses to interview question RA3a (management goals and assessment endpoints). B) Euclidean biplot of the themes and stakeholder groups in relation to the two axes. Farmer= blue triangle; government= green inverted triangle; industry= blue square; NGO= red diamond; scientists= pink circle.

A)



B)



Using PCA, twenty themes from the initial list of one hundred and one identified in the stakeholders' response loaded either negatively or positively on to either to of the two axes (appendix five B table 1); and therefore representing 71.08% of the variation. On axis one (figure 5.2A), the farmer, government and scientists groups scored positively; while the industry group, and to a lesser extent NGO group, scored negatively. On axis two the government, NGO and scientists groups scored positively (figure 5.2 a) and the farming and industry groups scored negatively.

Looking at the Euclidean biplot, there are four clear clusters of stakeholder groups and themes (figure 5.2B). Both the government and scientists groups scored positively in relation to both of the PCA axes. This suggests that these groups had similar views on what is required, in terms of MG and AE; however a number of themes do distinguish between the two groups. Both groups discuss the need to consider the future of agriculture, to identify future goals for agriculture in general (appendix 5A table 1.5 & 2.1); and drew comparisons with current conventional practices, stressing the need to regulate conventional crops which pose similar risks as GM varieties (appendix 5A table 2.1 & 2.4). However the government group raised a number of themes which the scientific group did not. These include the need for GM trialling and concerns about the implications on biodiversity (see section 5.3).

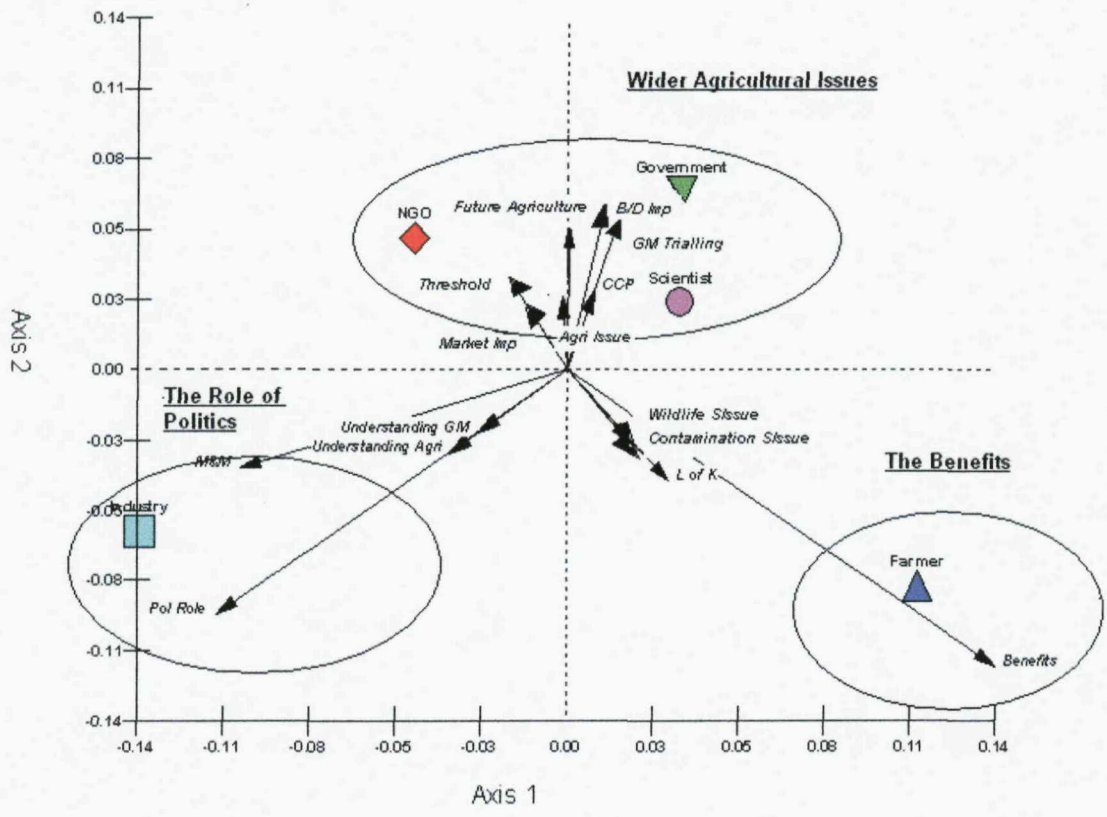
The industry group loaded in the opposite direction scoring negatively on both axes; this is indicative of contrasting views between the industry and government/scientists groups in relation to potential MG and AE. The industry group raised a number of issues including: the role of politics, the need for management and monitoring as well as the need for greater understanding of both GM and agriculture in general. The group's views in relation to the role of politics and the need for management and monitoring have been described previously (see section 5.3). The group identified a lack of understanding about GM technology and techniques even at a regulatory level (appendix 5A table 2.2). They also raised concerns about the level of general knowledge the public have about agriculture;

giving the example that, most people do not know "*every plant we eat has a virus on it*" ID (appendix 5A table 2.2).

The NGO group scored negatively on axis one and positively on axis two alongside a number of themes including the need to identify what was wanted from agriculture in the future and seeing a lot of the issues associated with GM crops as agricultural issues (see section 5.3). In relation to the future of agriculture, the group discussed the need to identify what is important for agriculture in the future and to consider GM within this context; they suggested the broader issues of agricultural sustainability and food quality should be drivers of this (appendix 5A table 1.4). Two other themes, thresholds and the market implications, also loaded on to the axes in the same direction as the NGO group, these have also been discussed previously in detail (see section 5.3). The farming group scored positively on axis one but negatively on axis two; diametrically opposite to the NGO group (figure 5B). Again this indicated of a divergence in opinion between the two groups in relation to potential MG and AE. The theme which differentiated the farming group the most from the others was the benefits. While benefit was identified as a key theme for government and scientist groups also, the farming group dedicated a much greater proportion of their response to this (table 5.1). A number of other themes are also specific to the farming group's response: the lack of knowledge the group felt they had, and the potential effect GM crops could have on wildlife. These have been described in detail previously (see section 5.3).

While the themes identified in the Euclidean biplot (figure 5.2B) enable each of the stakeholder groups to be differentiated, as described above; the themes, and therefore the stakeholder groups, can be characterized into three categories relating to the MG or AE that they identified (figure 5.3). These three categories give a broader illustration of how the they differ in their views of MG or AE.

Figure 5.3: Euclidean biplot of RA3a (MG and AE). The three underlying factors explain 71.08% of the variation between the stakeholder groups: The Role of Politics, The Benefits, and Wider Agricultural Issues.



5.4 Discussion

When discussing the MG and AE identified by the stakeholder groups, only two themes were brought up by two or more groups: the benefits and management and monitoring; these will be discussed first. The other themes mentioned, will then be discussed under three headings: environmental risks (those themes relating to specific environmental concerns the groups might have); regulatory process (those themes relating to the regulatory procedure); and wider issues (themes relating to issues not specific to GM crops, their environmental risks and regulatory process).

5.4.1 Benefits

A number of the stakeholder groups alluded to the potential benefits of GM crops and the need for their inclusion in the regulatory process (Chapter 3 section 3.4.3).

It is therefore unsurprising that three of the stakeholder groups (farmer, government and scientists) broached the issue of the potential benefits, when discussing MG and AE. Two topics relating to the benefits emerged from the groups' responses (appendix 5A table 1.1, 1.2 & 1.5): the first was the potential benefits that future GM crops might provide and the lack of emphasis placed upon these; the second related to the lack of consideration within the regulatory process of the benefits. It is of note that, while all the stakeholder groups identified benefits in their response to RA3a (MG and AE) and the aforementioned three groups discussed it to an extent that the benefits were classified as a key theme; as already mentioned the proportion of time the farmer group spent discussing benefits actually differentiated this group from the others when considering the variation in response between the groups (figure 5.2B). This signifies that for the farming group in particular the inclusion of benefits in both the regulatory process and in general consideration of GM crops is a very important MG. The fact that the farming group in particular identified the potential benefits of the technology is unsurprising considering their responses in the previous chapters, and the fact that a number of surveys categorizing farmer perception to GM crop also illustrate this (Anon, 2007; Hobbs et al., 1990; Kondoh and Jussaume, 2006), as does the rapid uptake of GM crops by farmers in countries which allow their commercial cultivation (James, 2005a). In the view of the farming group, in particular, but also the government and scientist groups, there is a need to evaluate, or include, the benefits of GM crops within the regulatory process.

The issues of benefits, and their incorporation into the regulatory process, was a central discussion topic at the EFSA Scientific Colloquium held between the 20th and 21st of June 2007. The Colloquium addressed the question of broadening the scope of the regulatory process to incorporate a benefit assessment; seeing an optional, not compulsory, inclusion of benefits as a step forward. Under current regulations there are elements in place to enable the assessment of the environmental benefits (table 5.2), these however are implicitly rather than explicitly implied. This may account for the common misconception that under existing regulations the inclusion of benefits is not allowed, illustrated in the recent ACRE report (2007a), which considered the issues raised by the FSE, they

state that "*Directive 2001/18 also makes no provisions for assessing both the potential risks and benefits... as the directive only considers the risks, evidence of any potential benefits... were not considered*" (ACRE, 2007a). The lack of an environmental benefits assessment currently is a result of how the regulations have been interpreted and imposed by the Member States and Competent Authorities, rather then a lack of scope in the regulatory process.

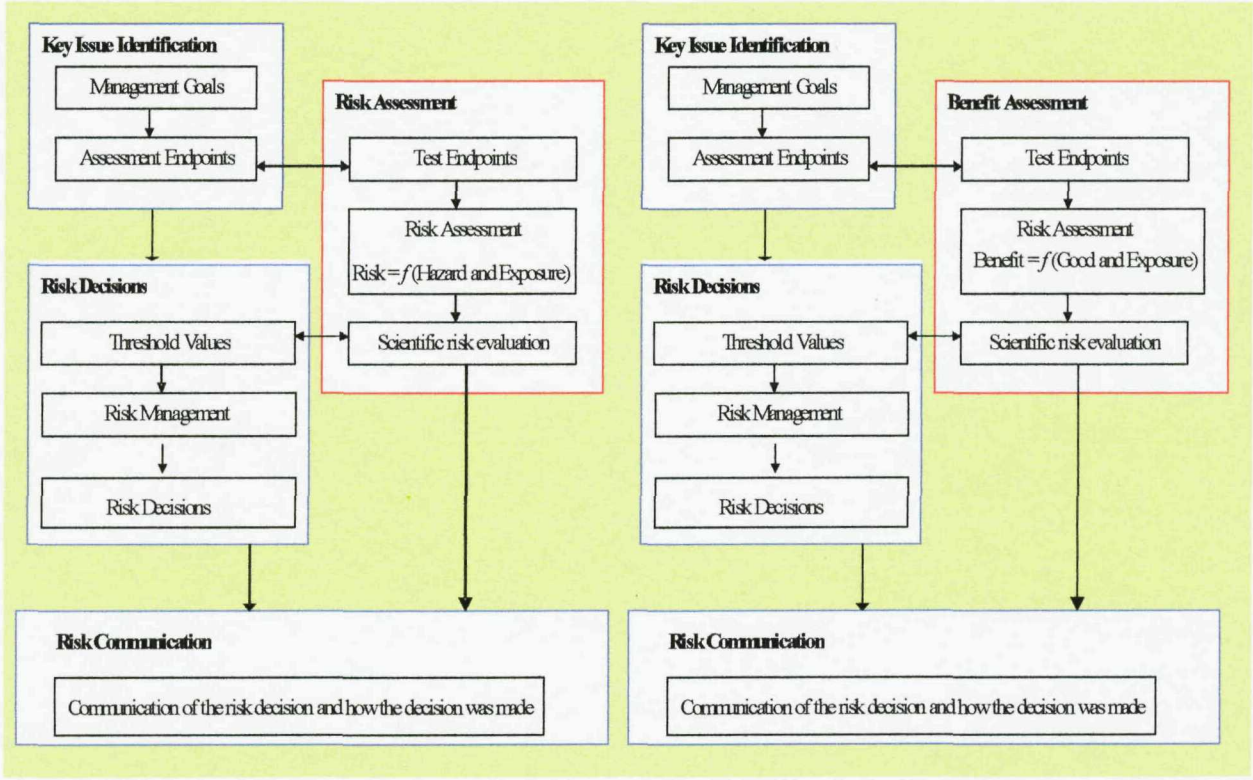
The explicit incorporation of a benefit assessment into the regulatory process would address the issues raised by the stakeholder groups; as long as the process was adequately communicated. By explicitly incorporating a benefit assessment, which ran in parallel to the risk assessment and worked in a similar way (see below figure 5.4), the benefits as well as risks can be assessed, and, where required, managed. This would allow the decisions made about the impact and commercialisation of GM crops to be based on a more holistic approach, which weighs the risks against the benefits. If benefit assessments were incorporated into the regulatory process and communicated well, then the benefit potential of future crops would be assessed prior to release by an independent panel of respected experts. This may negate the validity issues associated with the benefits of current GM crops (Amendola et al., 2005; Burkhardt, 2001). The need for an explicit assessment of benefits is clear and supported by findings of ACRE (2007a) and the DEFRA commissioned AR0317 project (Pidgeon et al., 2007) (see Chapter Three, section 3.4.2); both of which laid down a strong argument for the inclusion of benefits in GM risk assessment.

Table 5.2: The inexplicit references to the assessment of benefits within the current GM regulatory process (Van Der Meer 07- personal communication).

The Preamble of the Cartegena Protocol	There are a number of overarching international treaties to which EU regulations of GM have to adhere, one being the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (Introduction chapter x section y). In the preamble the CPB lays out a number of requirements to the Parties of this Protocol. One of which is "*recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.*"(CPB).
The Assessment of GM crops in relation to Non-GM crops	Annex II, Part B of Directive 2001/18 lays out the general principles of the environmental risk assessment (e.r.a). It states the need to "*identify characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations*" (Directive 2001). By drawing comparisons about the risks inadvertently you are also comparing the benefits, as crops which are shown to have the same or less risk associated to them when compared to their conventional counterpart, could be classed as beneficial.
Annex II Transition form Part C to Part D	Annex II of Directive 2001/18 outlines the principles for the environmental risk assessment (e.r.a). Parts A and B of Annex II lay out the objectives of and e.r.a and the general principles. Part C discusses the general methodological approach which includes the characterisation of the GMO and release as well as the steps within the ERA. These steps include the identification of characteristics which may cause adverse effects (hazards) and the evaluation of the potential consequences and likelihood of this occurring (exposure). Part D however differs; it talks about the environmental impact of the release, rather then the environmental risk. To evaluate the 'environmental impact' the environmental risks need to be considered within the context of the resultant environmental benefits and the risks posed by the mechanisms currently in place (the conventional counterpart) (Van Der Meer- Personal Communication 6th July 2007).

I propose that a benefit assessment could be incorporated into the process in the same way the risk assessment is (figure 5.4). In the paper by Johnson et al., (2007) we laid out the way the risk assessment should be integrated into the wider process of risk analysis. A benefit assessment could work in the same way; the derivation of a series of management goals, from which assessment and testable endpoints can be formulated. The actual benefit assessment would be done in the same manner as the risk assessment; only the identification of hazards would be switched for the identification of environmental benefits. The inclusion of a benefit assessment in the regulatory process is discussed in greater detail in the general discussion (Chapter Six).

Figure 5.4: The incorporation of a benefit assessment into the risk analysis process (adapted from Johnson et al., (2007))



5.4.2 Monitoring and Management

Two of the stakeholder groups (industry and NGOs) spent a considerable proportion of their response discussing monitoring and management. Both groups discussed the need to consider how the wider-scale implication of GM could be monitored (see section 5.3). Two assertions can be made: firstly, neither of the groups had previously brought up monitoring as a specific issue when discussing either the environmental implications or the regulatory assessment (Chapter Three, section 3.3; Chapter Four, section 3.4); secondly, while both groups identified the need for monitoring they appear to have very different views about what is required (appendix 5A table 1.3 & 1.4).

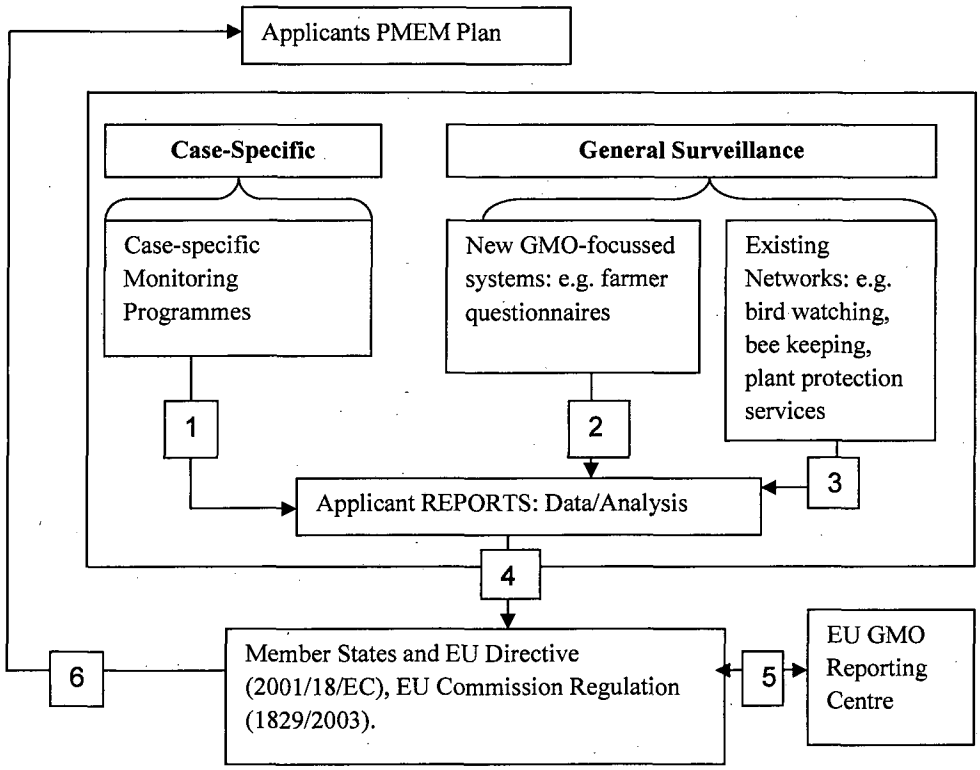
Post Market Environmental Monitoring (PMEM) of GM plants has two purposes *"to act both as control of biotechnology companies and the risk assessment"* (Kjellsson and Strandberg, 2001). In essence, it allows further investigation into whether the risk assessment has correctly assessed the hazards (and that the

information that the assessment is based on is correct) and also identifies any hazards or risks which were not initially identified in the risk assessment (Bartsch et al., 2006). PMEM is a requirement under Part C of Directive 2001/18 and also EU regulation 1829/2003 (Council of the European Commission, 2001b; Council of the European Commission, 2003b). PMEM is composed of two aspects (figure 5.5): case-specific monitoring and general surveillance (GS) (Council of the European Commission, 2001b; Council of the European Commission, 2003b).

Case-specific monitoring is not obligatory, but is a way of validating the risk assessment. Thus in cases where EFSA deem GM to pose no significant risks post risk assessment, then case-specific monitoring is not required. The issue however comes into play when other stakeholder groups disagree with either the review of the risk assessment made by EFSA or the scope of the initial risk assessment. The NGO group questioned the ability of the risk assessment to address the potential risks of wide-scale introduction (section 5.3), specifying the need for monitoring to address this; enabling specific risks, such as to health, resistance, or gene flow to be assessed. These risks would be hypothesis-driven so would not fall under GS but they also might be over-looked by the case-specific monitoring, as it is difficult to assess the risks in relation wide-scale adoption via small-scale field trials. This is a concern echoed in the 2005 Greenpeace report reviewing EFSA's decision to approve Bt maize 1507 (Lorch and Cotter, 2005). They criticised EFSA's assertion in the risk assessment that no adverse effect on non-target organism were anticipated and stressed concern that, because of this assumption, no case-specific monitoring was proposed (Lorch and Cotter, 2005). The way case-specific monitoring has been implemented in the regulations makes it very dependant upon the initial risk assessment. As part of the aims of any monitoring regimes, as identified by Kjellsson and Strandberg (2001), is to evaluate the risk assessment, ensuring that the correct conclusions about risks have been drawn, a monitoring regime that is only implemented in response to certain risk assessment decisions cannot evaluate the assessment fully and thus fails to fulfil these initial aims. This is something that needs future consideration, if NGOs are to have faith in both the regulatory process and the monitoring regime.

GS is required for all Part C releases under Directive 2001/18 (Council of the European Commission, 2001b) and is aimed at identifying unanticipated adverse effects. It enables the determination of whether an unusual effect has been observed (unforeseen weediness or changes in a populations biota) or if the effect is adverse, and that the adverse effect is associated with the GM plant or cultivation (Bartsch et al., 2006). GS was what both the industry and NGO groups were alluding to in their response (section 5.3). EFSA's paper gives a good overview of PMEM and in particular GS; here they stipulate that "*general surveillance is not hypothesis-driven but a general overseeing of the environment*" (Bartsch et al., 2006). This is a point over which the industry group raised concerns. They felt that by not being hypothesis-driven, the monitoring left itself open to criticisms over what is deemed important to monitor (appendix 5A table 1.3). EFSA and the EC, who set the Directives and Regulations, argued that GS should make use of existing surveillance systems or networks in addition to developing more focused monitoring systems (figure 5.5).

Figure 5.5: The requirement for monitoring and the data submission process under Part C of Directive 2001/18 taken from (Bartsch et al., 2006). Data from (1) CSM – if applicable- and (2) GS networks of applicants should be collected and analysed in a central data reporting point (3); where appropriate, additional data from existing networks are collected as well. (4) The PMEM reports shall then be sent to risk managers at Member State level and (5) forwarded for comprehensive analyses to a (so far not established) EU GMO reporting centre. (6) Authorities managing existing networks may adapt their General Environment Monitoring to the needs of PMEM monitoring which can then be consider in the applicants PMEM plan. Additional environment monitoring carried out under the responsibility of Member States can be integrated into PMEM plans as well. National Competent Authority might ask applicants to review its monitoring plan.



In relation to existing systems, (examples of which given in figure 5.5), the EFSA report does caveat their use by stating "*some might not be suitable for GM as they have been designed for other purposes*"(Bartsch et al., 2006). In terms of GMO focussed systems, the report stresses the use of farmer questionnaires, as do a number of others in the scientific and regulatory literature (ACRE, 2004; Commissie Genetische Modificatie, 2005; Sanvido et al., 2005; Wilhelm et al., 2004). This will be well received by the industry group who saw farmer surveys as the only way of achieving the PMEM objectives set (appendix 5A table 1.3), a point also supported by the biotech industry representative body EuropaBio in the literature (Tinland et al., 2006). From this, it would appear that currently the

requirement in relation to PMEM, and GS in particular, made by the industry group are being addressed by the regulatory approach. There is therefore little need for additional MG or AE to address this currently unless the requirements change. Change, however, is what NGOs are calling for. In a Greenpeace report by Lorch and Cotter (2005), they criticise GS calling it *"wholly inadequate"* and citing a number of reasons why this is the case. Central to their concerns, is the reliance on users with an interest in growing or processing GM crops to carry out the surveillance rather then independent scientific monitoring; and that monitoring is restricted to a subset of growers in representative regions which might mask effects more likely to be seen under extreme conditions (Lorch and Cotter, 2005). Certainly, for the time being, the position of the regulatory authorities towards GM PMEM and GS seems in line with that of industry rather then the NGOs; however with increasing criticism of the monitoring proposals, in particular GS, and the resulting criticisms of EFSA in relation to these from NGOs (Lorch and Cotter, 2005) it will be interesting to see whether the regulatory position towards PMEM changes.

5.4.3 Environmental Risks

Two groups, farmers and government, when asked about potential MG or AE raised issues relating to environmental concerns. Both groups identified that a potential MG of the risk assessment is that it should ensure against any negative implications GM crops might have on wildlife or biodiversity; with the farming group also highlighting the need to ensure against GM contamination (appendix 5A table 1.1 & 1.2). It is unsurprising that the government group identified minimising biodiversity implications as an AE (appendix 5A table 1.2), because they had previously discussed their concerns about this in relation to non-target effects of GM crop, where a fuller discussion of the groups' position in relation to the biodiversity implications can be found (Chapter Three, section 3.3.3). In the case of the farming group, however, neither the implication on wildlife or of contamination were identified as key themes when discussing the environmental risks (Chapter 3.3.1-3.3.4). In fact, the group mentioned only general concerns in relation to the non-target effects, and when asked whether they had any

environmental concerns about GM crops in general, (RA1a) the group specified that they had no such concerns (appendix 5A table 1.1).

The current regulatory process requires detailed risk assessments pertaining to the risks of gene flow and non-target effects (Council of the European Commission, 2001b; Council of the European Commission, 2003b), which should safeguard against any negative implications of GM both in relation to non-targets (wildlife) and gene flow (contamination). The farming group, however, might not be aware of the specific requirements of the regulatory process; in their own admission they lack knowledge about the regulatory process (see section 5.3). Greater familiarity with the process might negate any concerns the group have (Sjoberg, 2001), as their concerns could simply stem from not knowing what is required (in terms of safety assessment) in the regulatory process. There is, however, the suggestion that the more informed society get the more likely their views are to be polarised (Frewer et al., 1998). Certainly this could be the case with the farming group, who identified in their response that even "*if you test everything... it will come up with something else in our view*" (FB) suggesting that increasing their knowledge of what was incorporated within the risk assessment, might only make them more aware of what was missing. However, most social science commentators of the GM debate would agree that an informed society is better than a naïve one, reliant on media portrayal rather then their own understanding (Allum et al., 2002; Durrant et al., 1998; Durrant and Legge, 2006; Kasperson et al., 1988). This therefore makes a good argument for ensuring better communication of the regulatory process to all the stakeholders, something that certainly should be a MG of the regulatory process. Better communication should not just be in relation to communicating the risk decision, the process enabling the risk decision to be reached should also be communicated and if possible the context within which the decision was made.

The government group's identification of the need to consider the biodiversity implications of GM crops is more substantiated perhaps. Firstly, this is an issue the group had raised previously, adding strength to their concerns (Chapter Three,

section 3.5.3). Secondly, implications for biodiversity is a much more all encompassing issue then the two points the farming group raised and therefore not easy to address in the regulatory process. Biodiversity can be measured on a number of levels (MacDonald and Service, 2006), and ensuring biodiversity is maintained, if not improved, is a legal requirement under a number of EU and international treaties. Certainly, maintaining biodiversity should definitely be a MG of any risk assessment which is intended to ensure environmental safety. The question is, how the MG of maintaining biodiversity can be translated in to a series of assessment endpoints, and can they be transformed into viable test endpoints? Furthermore, is this not already being done by the current process? Legally, there are numerous international treaties and national laws which require the protection of certain aspects of biodiversity, whether these be: protected habitats, red listed species, areas/organisms of National importance, or government sustainability indicators. These would give a long list of priority habitats or species which require protecting and could be considered as the AE relating to the MG of protecting biodiversity. Clearly many would be irrelevant to the risk assessment and their removal would be easily justifiable; however it would give a starting point from which a number of appropriate testable endpoints can be identified. One of the biggest issues when assessing the impacts on biodiversity is the identification of a baseline from which measures of environmental change can be made; these will however be essential, if comparisons between the ecological effects of GM crop uptake by farmers are to be assessed. Potential baselines are discussed in the Royal Society's report (2003), considering GM crops in the context of modern agriculture and the environment. From this, it can be argued that it is feasible to use the protection of biodiversity as a MG, which can be translated into a series of assessments and then testable endpoints, as long as the identification of baselines is achieved. The second question is whether this is already being done in the current process. In terms of the requirements of the risk assessment, which tests for direct and indirect, immediate and delayed environmental effects (Council of the European Commission, 2001b; Council of the European Commission, 2003b), it would be hard to see what more could be required of the process, especially when comparing it to what is required for conventionally bred crops (Chapter One, section 1.5.1). However when considering these tests in isolation it is often hard to

relate them back to the initial MG or even AE. There is a strong argument to be made for the clear contextualisation of how the risk assessment fits within the wider process of risk analysis; how the testable endpoints tested in the risk assessment actually address the initial MG. The need to contextualise the risk assessment within the risk analysis process is discussed in depth in Johnson et al., (2007).

5.4.4 Regulatory Process

A number of the MG and AE identified by the stakeholder groups related to the regulatory process governing GM releases. These specifically included: the government group's discussion of GM trialling; the industry group's views of the role of politics; the NGO group's stance on threshold values; and the scientific group's need to draw comparisons with chemical risk assessment (see section 5.3). The MG and AE identified by the groups focused on very different aspects of the regulatory process; the government, industry and scientific groups focusing in on the risk assessment, although different aspects of this and from different perspectives, and the NGO group looking at the acceptable levels within the regulatory decision making process.

The scientific group considered the most fundamental aspect of this, the underlying principles. They perceived a need for greater inclusion of the knowledge gained from other areas where risk assessment was a requirement, giving chemical risk assessment as one example of this. There are those who would argue that GM risk assessment is principally based on what we have learnt from the much older science of pesticide risk assessment: "*The procedures for the risk analysis of Bt proteins have been developed based on those for pesticides. We don't need to reinvent the wheel here. We start with effective tests under standard conditions that fulfil the requirements of 'good laboratory practice'. However, since a chemical is not the same as a Bt protein, the test protocols have to be adapted accordingly*" (Romeis, 2006). It is understandable that the group would identify the need to draw comparisons with chemical risk assessment, as throughout the previous two chapters, (considering the environmental risks and

the regulatory process), the scientists group identified the need to draw comparisons with current conventional practices and the regulations governing them. Currently, the most stringent regulatory requirements for conventional agriculture to navigate is the pesticide regulations, refer to the European Directive (Council of the European Commission, 1991a). As pesticide risk assessment is a much older science, it is understandable that the group should refer to it as a potential learning tool for the much younger regulatory assessment of GM crops. The extent to which knowledge, taken from other forms of regulatory assessment, is used within GM assessment is unclear. While certain similarities can be drawn between GM regulatory assessments and others in terms of their requirements; a more comprehensive comparison of regulatory processes could be a future MG. By comparing the relatively new discipline of GM risk assessment to the more established discipline of chemical risk assessment, and justifying differences between the two; confidence in GM risk assessment may be improved. However, only for those who have confidence in the risk assessment process; those who lack trust in either the process, the science underpinning it, or those involved in it, are unlikely to have their concerns nullified. This is an example of how different stakeholder groups, with different levels of familiarity to the science and regulatory process underpinning GM risk assessment, as well as different levels of trust in the process, need very different things in terms of MG and AE from the regulatory process.

The government group focused on the scientific requirements of the risk assessment, identifying GM trialling as a potential MG or AE. Their concerns with the current regulatory process is that the field trialling, required prior to any application for commercial release (Council of the European Commission, 2001b), is not fully utilised. They would like to see greater attempts being made to consider the implications of large-scale commercial uptake, in particular discussing this in relation to gene flow. However the group did acknowledge that, in some cases, this is not always possible. The landscape-scale movement of transgenic pollen has gained a lot of scientific interest with a number of studies coming out just prior to the time of the interviews (Ramsay et al., 2003; Watrud et al., 2004). The need to incorporate landscape level predictions of environmental

risk assessments is something that has recently received increasing academic deliberation, Kapusta (2005) discussed the opportunities and limitations of this, but stresses the importance of landscape scale assessment in making spatially explicit estimates of exposure. There is clearly a strong argument for including landscape scale assessments as an assessment endpoint; however this would have to be considered against the practicality and feasibility of performing such assessments.

The industry group centred their response on the review process a notification for release has to undergo. They questioned the prominent role of politics in the decision making process, seeing this as an aspect of the regulatory process which needed addressing. Their concerns about the role of politics have in the regulatory process have been discussed in detail previously, (Chapter Four, section 4.4.3.2). Considering the proportion of time spent discussing the roles of politics, it is unsurprising that the group identified addressing it as a MG or AE; it also differentiated them from all the other stakeholder groups (figure 5.2B). The NGO group was the only other group to mention the role of politics and then not to an extent that it was considered a key theme. It is understandable why the industry group identified it as a potential MG, and the others did not, as it is principally the industry group who are directly affected by the lengthening of the regulatory process that results from the political influences. Both science and politics plays an integral role in any regulatory decision, in particularly with decisions that are as controversial as GM (Johnson et al., 2007). The balance between the two has been brought up by many of the stakeholder groups; and is therefore one of the central issues to have come out of this study. It will be examined in detail in the general discussion chapter (Chapter Six), as it could potentially have far reaching repercussions.

The NGO group differed from the others when discussing regulatory-based MG; rather than focusing their attention on aspects of the risk assessment or review process as the other groups did, the NGO group's attention centred on the threshold levels of acceptability. The group discuss thresholds in relation to

coexistence and the thresholds deemed appropriate (appendix 5A table 1.4). Current thresholds are based upon the liability regulations (Council of the European Commission, 2003a). The NGO group have expressed particular concerns about coexistence measures and threshold values when discussing their concerns about the regulatory process (Chapter Four, section 4.4.4). These concerns have been echoed in the NGO literature (Contiero, 2007; Etty, 2007; Friends of the Earth, 2003c). Identifying acceptable thresholds for level of risk is a key issue to the NGO group. Thresholds are often considered as amber lights to warn regulators of possible unacceptable environmental change and are considered to be "*the link between management targets* [i.e. MG] *and a hypothesis testing approach to science* [the risk assessment]" (Rogers and Biggs, 1999). While scientific input is important to direct where threshold values are to be set, it cannot be the sole contributor to them, as "*acceptable risk cannot be determined purely scientifically: science can predict the likelihood certain effects, but non-scientific criteria must be included in the process judging their acceptability*" (Johnson et al., 2007). The effect 'non-scientific criteria' has had on threshold levels has been seen with the tightening of labelling laws under EC Regulation 1830/2003 in 2003 (Council of the European Commission, 2003b), which changed the labelling threshold for GM from 1% to 0.9%. This came on the back of calls from various stakeholders, in particular NGOs, to lower the labelling threshold to under 1% (Friends of the Earth, 2003a; Hu et al., 2005; The Soil Association, 2004; The Soil Association, 2006); however, it did not go far enough for some who required a threshold to be set at 0.1% (Friends of the Earth, 2003d; The Soil Association, 2006). Stakeholders' inclusion in the setting of acceptable threshold values certainly makes for a valid MG; and one it would appear that is already in place under the current regulatory process, although not, it seems, to the satisfaction of all concerned.

5.4.5 Wider Issues

When considering the key themes identified, two of the stakeholder groups, the NGOs and scientists, discussed potential MG or AE which related to wider issues; that is issues falling outside the environmental risks of GM crops or the regulations which govern them. Both groups alluded to the need to consider GM

crops, the environmental risks and regulatory process, within the context of agriculture in general. Indeed it is the identification of the wider issues which sets these two groups, as well as the government group, apart from the farming and industry groups in the PCA analysis (figure 5.2B). When discussing their concerns about the environmental risks of GM crops (Chapter Three), all three identified that some of the risks were more issues of agriculture rather then GM. The government and scientist groups also identified the need to consider GM crops in comparison with current conventional practices and in the context of agriculture or future agricultural goals. The concerns the groups have, in relation to agriculture in general, are discussed in detail in the previous chapter (Chapter Three, section 3.4.1); the groups saw the need to consider the goal for agriculture more generally, as a key issue when setting MG or AE for GM crops. This view differentiates them from the industry and farming groups who concentrated their response on aspects specific to GM crops, (the role of politics in GM regulation in the case of industry, and in relation to the farming group the acknowledgement of the benefits GM crops might provide).

The scientists group stressed the need for a MG which sets out what is required from agriculture in the future both in terms of production and environmental stewardship (see section 5.3); such that, within this context, GM can then be evaluated. This concern was echoed in a Royal Society report (2003) which emphasised the need for a decision to be made about the level of biodiversity wanted in the UK and how this is going to co-ordinated across the landscape of Britain. That "*only when we know what we want can we decide which technologies are appropriate*" (The Royal Society, 2004). It is not surprising that the scientist group set out the need for MG pertaining to what is required from future agricultural production as, in both previous research chapters (Chapter Three, section 3.4.1; Chapter Four, section 4.4.5), the group drew comparisons with conventional agricultural practices and stressed the need to consider GM, the risks and regulatory approach, within the context of agriculture in general. The need to consider the way GM is regulated in relation to how other conventionally bred crops are regulated, and to bring the two more inline, is one of the key points in the ACRE report (2007a) on managing the footprint of agriculture. The report

looked at the need to consider GM within the wider context of agriculture, and therefore future agricultural goals. These goals were recently outline by the then Environmental Secretary Right Honourable David Miliband MP in his speech at the Royal Agricultural Show: "*Our goals for farming should be: To build a profitable, innovative and competitive industry meeting the needs of consumers; to fulfil its unique role in the countryside by making a net positive contribution to the environment, managing its risks, especially animal health risks, effectively; and to contribute to the long-term sustainability of rural communities*" (DEFRA, 2006). GM crops could be evaluated in relation to these goals. The second point made by the Right Honourable David Miliband MP '*making a net positive contribution to the environment*', in part is addressed by the risk assessment in the current regulatory assessment, although an explicit benefit assessment would also be required if a net positive contribution was to be established. There is need for GM crops to be considered within the context of what is required from agriculture in the future. It would lead to a better assessment of the risks and potential benefits of the crops as well as their usefulness; it would also mean that the crops would not solely be considered on their scientific merits (in terms of risk) but also their economic and potentially societal merits too. This can only benefit the regulatory process. The government's goals for agriculture could be one of a number of MG that could be used to drive the formation of MG specific AE that then can be formulated into testable endpoints, the drivers of the risk (and potentially benefit) assessment (see Chapter Six). By having clear goals, such as the government's goals for farming, driving the regulatory process, it enables the risk assessment, and indeed the regulatory decisions making process, by providing a point of reference to refer back to in order to justify the decisions made. By contextualizing risk assessment and regulatory decisions within a wider society-driven management goal, it will enable concerns which are non-science based (and therefore not addressed in the risk assessment) to be directed away from the risk assessment towards the over-arching goals. This is much more appropriate then the situation at present where the scope of the risk assessment is questioned for not incorporating these concerns.

The NGO group identified the need to address the intensification of agriculture in general (see section 5.3), placing the environmental impacts of agriculture further up the agenda in terms of farming policy which reflects a sustainable approach to farming. When discussing the environmental risks (Chapter Three, section 3.3.3), the NGO group stated their concerns about the risks of agriculture in general, especially in relation to the non-target effects, reiterating a concern supported in NGO literature (see Chapter Three, section 3.4.6). It is unsurprising, therefore, that the group identified the need to consider the environmental impact of agriculture *per se* as a potential MG. While, as discussed above, future goals for agricultural production should certainly be a driver of the regulatory process, and therefore a MG, the question is whether the NGO group's specific concerns about agriculture in general should be driven through GM crop regulation. It would be fair to say that the GM debate has been an effective way of getting the environmental impacts of agriculture in general more recognition, the FSE were a good example of this. Clarity about what is required from agriculture in terms of production and environmental protection is clearly needed. However, it would be unfair to place hurdles solely in front of the commercialization of GM crops, based on broader concerns about agriculture in general. Therefore the concerns the group raises about farming policy resulting in unsustainable intensified agricultural production is something that needs to be addressed by agricultural policy in general, rather then GM regulations specifically, and then agricultural policy and the goals it sets can be used to drive the GM regulatory process.

5.5 Conclusions

There is a need for the explicit assessment of benefits within the EU regulatory process. While there is scope in the current regulations for this to be done, the fact is, very few of the Member States have interpreted this and incorporated it into their National Laws. As a result, the risks are often taken out of context, especially by wider society and those apposed to GM, and this needs to be addressed.

The environmental risks GM crops pose also need to be considered within the broader context of agriculture in general. Future agricultural goals in terms of

agricultural productivity and environmental stewardship need to be identified. These should then be used to drive the regulatory assessment of GM crops.

Following on from the last point, there is also a need to place the risk assessment firmly within the broader context of the risk analysis. By contextualizing the risk assessment within the risk analysis framework of defined goals, endpoints and thresholds, decisions about risks are more readily justified, negating some of the criticisms of the process at present.

Chapter Six

General Discussion

6 Chapter Six: General Discussion

The aim of this research was to explore the hypothesis that various stakeholder groups had different perceptions of the environmental risks associated with deliberate release of GM crops and therefore placed differing requirements upon the regulatory process. This was conducted via three research aims: the first and second were to assess different stakeholders' perceptions of the environmental risks associated with the deliberate release of GM crops (Chapter Three) and the current regulatory process (Chapter Four); the final identified management goals and assessment endpoints (Chapter Five). To achieve these aims, two objectives were set: the first was to identify the perceptions of each individual stakeholder group in relation to each of the research aims; the second was to assess the areas of difference and commonality between the groups. The findings of this study not only have relevance to the GM debate, but to all scientific innovations which are introduced into an increasingly risk averse society (Beck, 1992; Elkstrom and Askegaard, 2000). The general discussion will address prominent aspects of the stakeholders concerns which have appeared across the research objectives and aims.

6.1 Summary of the key findings

By considering the key themes identified by the stakeholder groups using the 'proportional occurrence' scores, and also how the stakeholder groups differed (PCA analysis), the research objectives were achieved (figure 6.1). The two tables below (6.1 and 6.2), summarize the findings of the 'proportional occurrence' analysis and PCA respectively. Taking table 6.1 for example, column one represents the findings of the 'proportional occurrence' analysis undertaken in chapter three. The first point in column one of table 6.1, "the need to compare the environmental risks posed by GM crops to those posed by the current conventional counterpart", is drawn from a number of findings in chapter three, where stakeholder groups identify the need to draw comparisons between current conventional practices and wider agriculture in general (see table 3.5, page 147). All the following points in column one (table 6.1) also summarizes the findings of the 'proportional occurrence' analysis undertaken in chapter three. Likewise, columns two and three summarize the findings of the proportional occurrence analysis in chapters four and five respectively. The same principle applies in table

6.2 which presents the findings of the PCA. The first paragraph in column one relates to the raw PCA findings in figure 3.1 (page 127). These are then discussed in detail on page 164, in section 3.4.8.1 (Chapter three). Indeed the whole of section 3.4.8 discusses in depth the findings summarized in column one of table 6.2. Columns two and three summarize the findings of the PCA in chapters four and five. More detailed discussions of the findings summarized in columns two and three (table 6.2) can been found in sections 4.4.1-4.4.4 and 5.4.1-5.4.5.

Figure 6.1: Addressing the research aims through the quantitative identification of themes

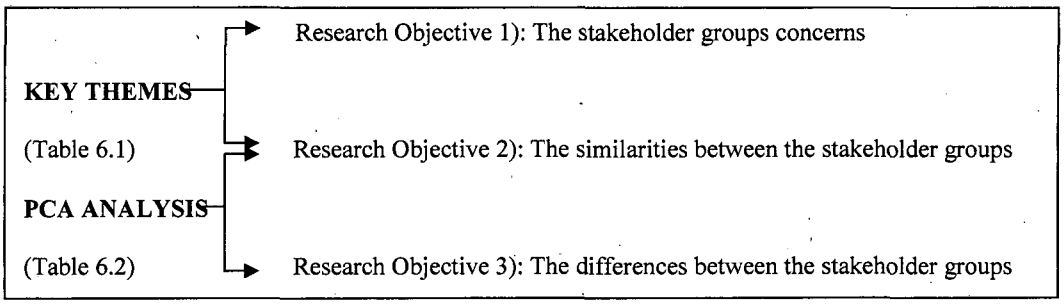


Table 6.1: The key themes identified by the stakeholder groups using the proportional occurrence scores

6.1.1 Key themes representing the stakeholder groups' main concerns		
6.1.1.1 Environment risks (Chapter Three)	*6.1.1.2 Regulatory process (Chapter Four)*	*6.1.1.3 Identification of management goals and assessment endpoints to address the stakeholders concerns (Chapter Five)*
The need to compare the environmental risks posed by GM crops to those posed by the current conventional counterpart. The need for the assessment of risk to be made on a case-by-case basis. The need for the benefits of GM crops to be assessed alongside the risks. The need for the regulatory process in assessing the environment safety of deliberate releases. A specific concern about the environmental risks associated with gene flow of the transgene. The NGO group had wider concerns relating to uncertainty and the potential for GM to intensify and thus industrialise agriculture. GM crops potential to alter farm management practices was considered in a different way by the stakeholder groups than other risks such as gene flow and non-target effects.	The stakeholders had varying perceptions of the suitability of the current regulatory process and the adequacy of its scope. The roles of various stakeholders within the regulatory process was questioned, in particular those of EFSA and politics. The need for the regulatory process to be seen in comparison to what is required for current conventional practices. The NGO group had a number of wider concerns relating to: the underlying philosophies the regulatory process was built upon, how it had dealt with the threats they perceived from genetic contamination and coexistence, and the issue of regulatory centrality.	The inclusion of an explicit benefit assessment. The need to address certain issues with current management and monitoring practices. To ensure GM crops do not have negative impacts on biodiversity. In relation to the regulatory process the stakeholders identified the need to: address the role politics has particular in relation to the review process, to re-evaluate threshold levels, to consider issues associated with GM trialling in particular, gaining more from them, and to draw experience from chemical risk assessment. For GM to be considered within the context of what is required from agriculture in general rather then separately.

Table 6.2: The differences in the stakeholder groups' responses found using the PCA results

6.1.2 The similarities and differences between the stakeholder groups		
6.1.2.1 Environmental risks (Chapter Three)	*6.1.2.2 The regulatory process (Chapter Four)*	*6.1.2.3 Management goals and assessment endpoints*
The government, industry and scientists groups concentrated their responses on the scientific risks, while the farmer and NGO groups discussed their environmental concerns in the context of wider issues. The industry and scientists groups stipulated the need for a case-by-case approach; whereas the government group discussed the need for GM regulation in general. The farmer group identified the need to place GM in the context of agriculture in general. The NGO group were concerned about the wider issues such as uncertainty and the potential for GM to intensify agricultural production. The industry and NGO groups looked at the wider issues in relation to the risks posed by GM gene flow. The farmer, government and scientists groups identified that GM gene flow could cause environmental risks and that these risks need to be seen in the context of current practices. The government group identified the effects to non-targets as a specific issue of GM crops, stipulating the need for regulating them. The others saw non-target effects more as an agricultural issue, one to consider within an agricultural context. The NGO view was that	The NGO group discussed issues such as coexistence and the economic implication of GM crops; whereas the government, industry and scientists groups discussed the roles of various stakeholders when discussing the regulatory process. The farmer group identified their lack of knowledge and the need for GM trialling and the FSE. The farmer, NGO and scientists groups compared GM regulations with those governing current conventional practices; whereas the industry group saw the regulations as evolving and suitable, although they raised the question about public understanding. The government group, on the other hand saw the regulatory process as too broad and spent time discussing the roles of politics and EFSA. The farmer, government and scientist groups identified the potential benefits of GM crops and the thoroughness of the regulatory review process. Industry discussed the roles of politics in the process and the issues of regulatory consistency; whereas the NGO group discussed the role of EFSA and felt that the review process was poor, stating issues with substantial	The government, NGO and scientists groups all identified the need to consider GM crops in the context of what was required from agriculture in the future. The NGO group discussed threshold requirements and the market implications for GM crops, while the government and scientist groups discussed GM trialling. The farming group identified the benefits of GM crops, while

GM could perpetuate the risks already posed by conventional agriculture; whereas farmer, industry and scientists groups saw it as potential having benefits. The farmer and industry groups saw GM crops as potentially benefiting both the environment and agriculture; as it will reduce pesticide reliance and improve farming flexibility. The NGO group saw GM as potentially being detrimental to the environment through its ability to further industrialise agricultural production. All except the industry group identified alterations to farm management as an agricultural issue.	equivalence and contamination. The NGO group called for greater transparency and for the process to be regionally decided upon rather then centrally. The government and scientists groups saw the process as constantly evolving and in the case of the scientists group too narrow when discussing improvements. The scientists and farmer groups recognized the necessity to include the benefits in the regulatory assessment; the industry group stressed the need for better regulatory consistencies.	industry discussed the roles of politics, the monitoring and management of the crops as well as the issues surrounding public understanding of both GM and agriculture.

6.2 General discussion of the key themes

The stakeholder groups identified a wide array of issues when discussing the potential environmental risks the deliberate release of GM crops could pose and how the crops were regulated; they also identified a range of management goals and assessment endpoints. The issues recognized by the groups differed, with certain themes only mentioned by one group, pinpointing areas where there are clear divergences in concern. There were, however, a number of issues with which all the groups identified, although in some cases their specific concerns in relation to these differed; these provide platforms of commonality.

Three issues encompass a number of the stakeholders concerns:

1. The need to draw comparisons with current conventional practices; when evaluating the environmental risks and considering the regulatory practices, to address current imbalances in the regulatory approach; enabling GM to be seen within a wider agricultural context, possibly driven by the future requirement that will be placed upon agricultural production (see section 6.2.1).

2. The need for an explicit assessment of the potential benefits GM crops provide, both in terms of environmental benefits, but also societal, agricultural and economic benefits. This could allow the environmental and wider impacts of the crops to be evaluated, something which is not possible when considering the risks alone (see section 6.2.2).

3. The role societal concerns should have in the regulatory process and the weight that this is given in relation to the scientific evaluation of risk in the regulatory decision making process, in particular the voting of the Member States (see section 6.2.3).

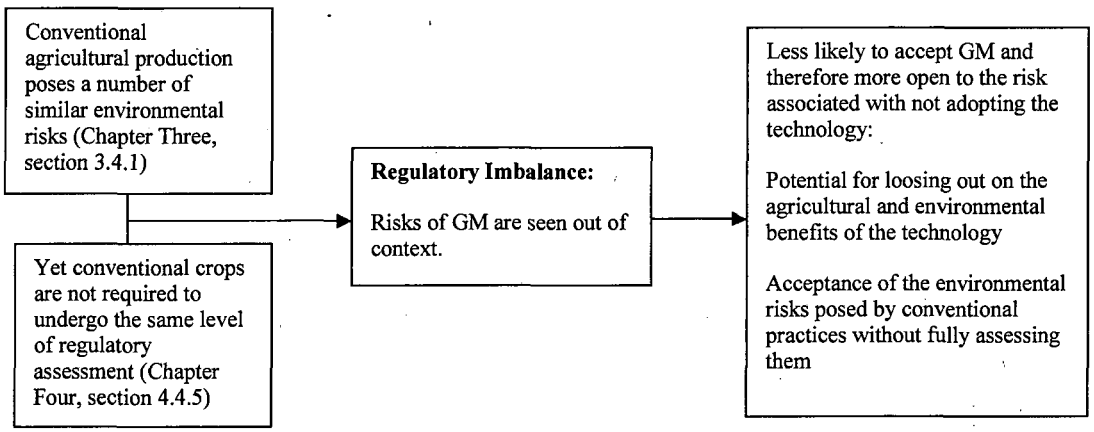
These three issues, as well as encapsulating the common concerns of the stakeholder groups in relation to GM crops, also can be applied in other areas of scientific innovation (see section 6.2.4). These have wider implications, as they

illustrate a number of fundamental requirements made by stakeholders when it comes to the regulation of novel and potentially risky scientific innovation.

6.2.1 The need to consider GM crops in comparison to current conventional varieties

The need to draw comparisons with conventional practices, both in terms of the risks GM crops pose (Chapter Three, section 3.4.1) and how they are regulated (Chapter Four, section 4.4.5), was identified by all the stakeholder groups and illustrated in figure 6.2.

Figure 6.2: The concerns expressed by the stakeholder groups in relation to the regulatory imbalance between conventionally bred and GM crops, especially those expressing similar traits for example, herbicide tolerance.



The regulatory imbalance between conventional and GM crops (Chapter Four, section 4.4.5) was identified by the stakeholder groups as something which required addressing. Current EU regulations saw the process of GM as novel and thus posing unique risks to both the environment and human health (Nap et al., 2003) and, as such, required separate regulation (Council of the European Commission, 2001b; Council of the European Commission, 2003b), despite, in some cases, presenting comparable risks. This resulted in the environmental risks posed by GM crops often not being placed in context with the risks posed by conventional practices. This was a particular concern of the stakeholder groups (Chapter Three, section 3.4.1; Chapter Four; section 4.4.5 and Chapter Five,

section 5.4.5), as the environmental implications of GM crops can not be properly evaluated unless they are considered within this context. In particular, many of the stakeholders expressed their concerns about the potential for environmental benefits to be passed up due to the lack of comparison with current conventional practices (discussed later, section 6.2.2) and the blind acceptance of the risks posed by conventional agriculture. The monarch butterfly and the furore which surrounded that, is a perfect example of this; not only does it highlight the implication of considering the intrinsic hazards out of context of the potential exposure (Chapter One, section 1.3.3), but the subsequent studies also illustrated what happens when only the risks of the GM are considered without any comparison to the current situation. These studies showed that monarch larvae were more at risk in fields sprayed with conventional pesticides, which are subject to spray drift, then they were in Bt fields (Sears et al., 2001; Standley-Horn et al., 2001), contradicting the initial concerns that Bt crops would increase the risk to monarchs.

By addressing the regulatory imbalance, it will not only address one of the stakeholders' key concerns, it will also allow the environmental risks posed by GM crops to be seen within the wider context of agricultural practice in general, thus enabling a more focused evaluation of GM as an agricultural tool rather then a novel product. A straightforward way of addressing this imbalance would be, either: the up-regulation of conventional agriculture, requiring conventional crops which contain similar traits to undergo equivalent regulatory assessments as the GM varieties; or the down-regulation of GM to bring it more in line with the regulatory system currently governing conventional practices. Both, one feels, would be met with ardent opposition. The regulatory process might therefore require more substantial adaptation, in order to address the imbalance between conventional and GM crops, without making the process overly bureaucratic and unmanageable. The ACRE report (ACRE, 2007a) and DEFRA funded AR0317 project (Pidgeon et al., 2007) represents a change in the way the UK government is thinking about regulating GM and agriculture in general.

Currently, both the scientific risk assessment and the subsequent evaluation of GM crops are driven by one regulatory objective (assessment endpoint): "*...to protect human health and the environment...*" (Council of the European Commission, 2001b). Protection of the environment (and human health for that matter) is very open-ended in terms of the ways in which it can be interpreted, as it does not lend itself easily to identifiable testable endpoints. While the Directive stipulated a comprehensive list of requirements in Annex III (Council of the European Commission, 2001b) that needed to be included in the regulatory assessment, these requirements are often questioned in terms of their scope by those opposing the regulatory process (Friends of the Earth, 2004; Friends of the Earth and Greenpeace, 2006; NRC, 2002), who then require further testing, on the basis that not everything which could be impacted by the deliberate release of the GM crop had been tested. The sole objective to ensure 'environmental protection', also often falls short of the overarching goals the stakeholder groups wished the regulatory process to achieve, by only protecting human health and the environment, concerns relating to economic and societal health are dismissed. I suggest that more widely encompassing regulatory objectives need to be identified from which clear testable endpoints can be deduced. These regulatory objectives need to be considered within a much broader context that is representative of societal concerns about agriculture in general, and within which both GM and conventional crops can be evaluated.

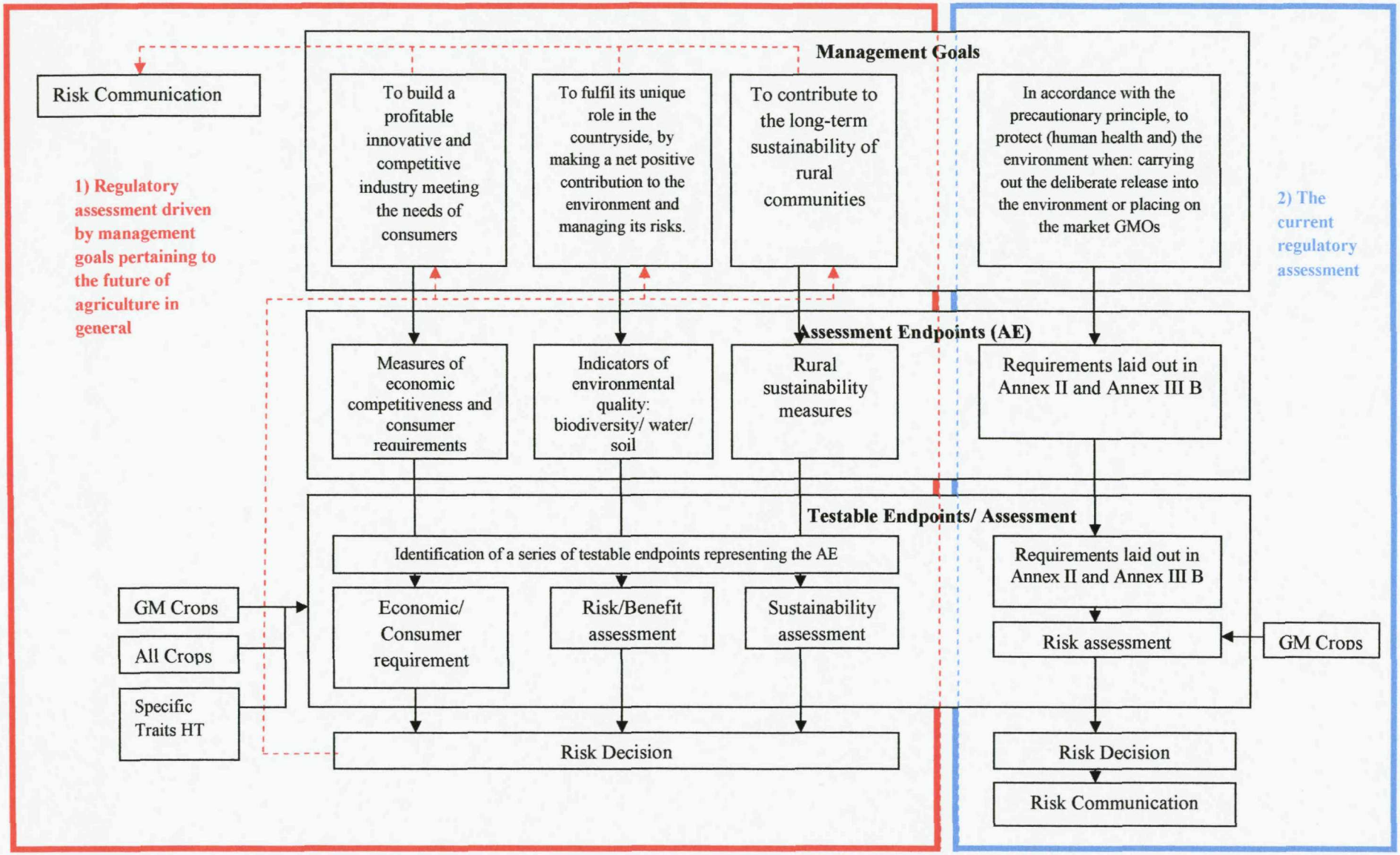
The stakeholder groups identified a number of management goals relating to the recognition of what is required from future agricultural production, both in terms of food production and environmental protection. These could be used to set out clear objectives for the risk assessment of GM crops and would enable them to be compared against their conventional counterparts (Chapter Five, section 5.4). Producing a series of agricultural goals within the context of which GM, or any agriculture technique or tool, is evaluated, will enable a more holistic and justifiable regulatory process. The UK government has already proposed a series of agricultural goals (Chapter Five, section 5.4.5) that are much more representative of the stakeholders' concerns then those currently driving GM regulations (figure 6.3). The stakeholders identified economic and societal goals

as well as scientific goals and required the benefits to be considered alongside the risks. By assessing GM crops within this more holistic context, regulatory decisions pertaining to the crops being deliberately released can be justified back to original management goals that take on board a much broader spectrum of societal concerns. This structured approach to formulating a qualitative regulatory assessment from what are essentially qualitative societal concerns provides a transparent, objective decision making process, essentially for a robust and trusted regulatory system.

The need to visibly include the social context of risk into the regulatory framework has been identified by the International Risk Governance Council in their 2006 White Paper on Risk Governance (Renn, 2006); which is referred to as 'the white paper' from this point onwards . The need to include a societal context for risk and risk decisions within the risk governance framework is one of the two major new innovations to the risk framework the white paper proposes. This would give equal importance to contextual aspects of risk as it does to risk assessment, management and communication. The contextual aspects include the structure and interplay of the different actors dealing with risks, in particular taking into account the range of different perceptions of the risks and their consequences a variety of stakeholders would have. These contextual aspects would either be directly integrated in a model risk process (previously comprising of risk assessment, risk management and risk communication); or, form the basic conditions for making any risk-related decisions. The white paper also makes three major value-based premises and assumptions; the first of which supports the conclusions drawn in this thesis. That is that, "*the framework is inspired by the conviction that both the 'factual' and the 'socio-cultural' dimensions of risk need to be considered if risk governance is to produce adequate decisions and results. While the factual dimensions comprises physically measurable outcomes and discusses risk in terms of combination of potential – both positive and negative-consequences and the probability of their occurrence, the socio-cultural dimensions emphasises how a particular risk is viewed when values and emotions come into play.*" (Renn, 2006). The white paper supports our argument that there

is a clear need to include an assessment of societal concerns alongside the evaluation of the scientific hazards when making regulatory decisions about risk.

Figure 6.3: The current regulatory process (boxed in blue) and a proposed adaption to the regulatory process, driven by the government's goals for future UK agriculture (boxed in red). While the current process only considers GM crops, the proposed process could compare both GM and conventional varieties. The proposed regulatory process would explicitly look at both the risks and benefits as well as the social and economical implications; unlike the current process where goals are purely to protect human health and the environment, so focus solely on the risks posed by the crops.


Management Goals
Risk Communication
To build a profitable innovative and competitive industry meeting the needs of consumers
To fulfil its unique role in the countryside, by making a net positive contribution to the environment and managing its risks.
To contribute to the long-term sustainability of rural communities
In accordance with the precautionary principle, to protect (human health and) the environment when: carrying out the deliberate release into the environment or placing on the market GMOs
1) Regulatory assessment driven by management goals pertaining to the future of agriculture in general
2) The current regulatory assessment
Assessment Endpoints (AE)
Measures of economic competitiveness and consumer requirements
Indicators of environmental quality: biodiversity/ water/ soil
Rural sustainability measures
Requirements laid out in Annex II and Annex III B
Testable Endpoints/ Assessment
Identification of a series of testable endpoints representing the AE
Requirements laid out in Annex II and Annex III B
GM Crops
All Crops
Specific Traits HT
Economic/ Consumer requirement
Risk/Benefit assessment
Sustainability assessment
Risk assessment
GM Crops
Risk Decision
Risk Decision
Risk Communication

Any alterations to the regulatory process, and what is required under it, will have repercussions; especially alterations which at first glance seem to lengthen the regulatory process and / or increase its cost. Certainly, broadening the regulatory scope of the process will appease a number of its critics who call for the inclusion of benefits, economic assessment, and a measure of societal concerns (Chapter One, section 1.6). The concern is that it will only appease them as it will add further delay to the process rather than because the alterations address their concerns. A strong argument could be made, that some of those who object the loudest to GM will never be satisfied until a total ban is in place; and as such, the suggested additions to the process will not quieten their objections about GM crops they will only act as a way for them to elongate a process which is already a time consuming and financially expensive (especially if conventional crops were also required to go through it).

One way of negating this would be for new traits (for example herbicide tolerance), to be investigated. This would be independent of whether they are GM or conventionally produced (i.e product based rather than process based). Thus new varieties could be grouped according to trait (for example herbicide tolerance) and these could then be investigated in parallel and compared against one another according to the environmental/economic/and social risks and benefits they pose. This way the stakeholders' concerns that conventional varieties posing equivalent risks will be addressed and GM crops will be considered in the wider context of what is required from agriculture in general and not just in terms of the environmental risks posed.

6.2.2 The need for the explicit assessment of benefits

When the regulatory process was first formulated in the late 1980s the environmental assessment of GM was not intended to be done in a vacuum. According to Piet van der Meer who was involved in the first construction of European GM regulations "*the environmental risks were meant to be considered within the context of the benefits, the risks of not utilising the technology and the risks posed by the conventional practices already in use*" (van der Meer, 2007- personal communication).

Indeed within the current regulatory process there is the scope to include an assessment of benefits (see Chapter Five, section 5.4.1) but because the benefits were only implied within the regulatory assessment, rather than explicitly, when it came to their adoption into the national laws of the Member States, they were often neglected. There are a number of reasons for why this might have been the case, ranging from the governments' wish to been seen to remain neutral in their regulation of GM crops (Streiffer and Hedemann, 2005) to the concerns of industry that the inclusion of a benefit assessment would be another regulatory hurdle (Little, 2006). Now, however, the stakeholder groups identified the clear need for an explicit consideration of benefits within the regulatory process, as it enables the environmental implications of GM adoption to be evaluated rather then just the environmental risks.

Even though the current process lacked the explicit benefit assessments, in some cases the benefits are still being assessed, only they are not recognised as such. For example, in assessing the risks GM crops pose, there are cases where the risk is less than, or similar to, those posed by conventional agriculture. Potentially, therefore, the GM variety is beneficial. The benefit assessment in these cases is an artefact of the risk assessment and simply required better communication that a lack of risk could, in most cases, equate to a potential or comparative benefit. There are, however, other potential environmental benefits that are not assessed this way, as they are not perceived as risks initially. For example, the potential for GM HT crops to reduce tillage requirements, or the change to more benign chemical pesticides as a result of GM adoption (Chapter One, section 1.2.1). In these cases, an explicit assessment of the benefits is required to enable the environmental impact of adopting GM agriculture in Europe to be properly appraised.

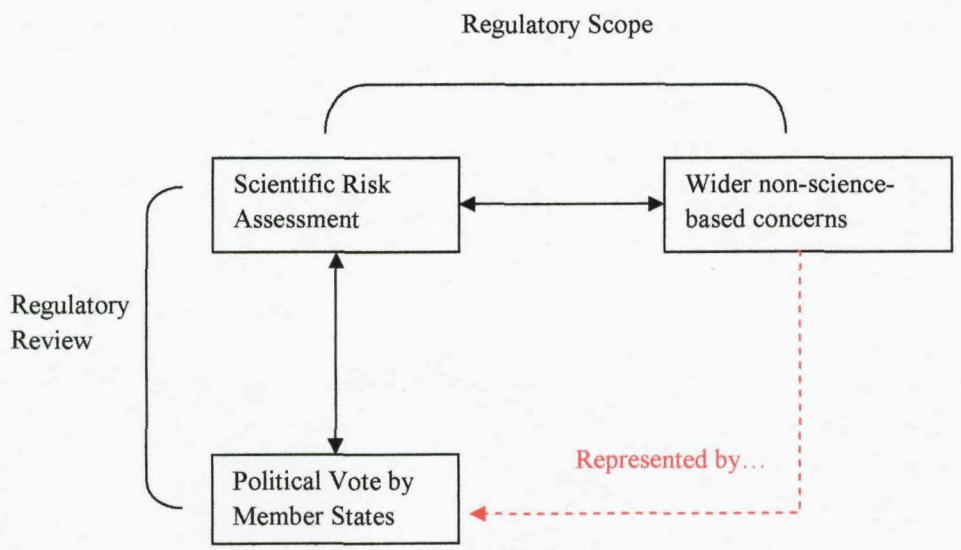
While the explicit inclusion of a benefit assessment within the current regulatory process would negate the issues raised by the stakeholders in relation to the lack

of the environmental benefits being evaluated, it fails to address their concerns about the wider societal and economic benefits the crops might provide. These however would be assessed under the proposed adaptation to the regulatory system discussed previously (section 6.2.1, figure 6.3), which considers GM crops in a much wider context than just the environmental risks.

6.2.3 Addressing the roles scientific and societal concerns have in the regulatory process

The current GM crop regulatory process is science-based; meaning that only those environmental (and human health) risks that can be scientifically quantified and evaluated are considered. It also requires expert panels of independent scientists to undertake the risk evaluation. There are two issues which have surfaced in relation to this and they are voiced, in particular, by the opposing ends of the debate, figure 6.4. The first is in relation to the regulatory scope, and whether the inclusion of purely science-based concerns is suitable when addressing the environmental risks, a concern most notably raised by the NGO group. The second relates to the weight the scientific evaluation should be given within the political decision making and voting by Member States, a major criticism made by the industry group.

Figure 6.4: The two regulatory issues: The first, in relation to its scope, pertains to the inclusion of wider non-science-based concerns and the current predominance of the scientific risk assessment and evaluation process. The second is to do with the regulatory decision making and whether it should be based purely upon the scientific risk assessment or wider 'political' issues. There is a link between the two (red dashed arrow), which is the argument that, in the current process, the politicians represent the wider societal concerns.



The need to include, or at least address, wider societal concerns was a common issue acknowledged by all the stakeholders (Chapter Three, section 3.3 and Chapter Four, section 4.3). The current regulatory process does not have the scope or the remit to do this; its objective is to evaluate safety (Council of the European Commission, 2001b; Council of the European Commission, 2003b), rather then make judgements about what agriculture should look like, or the necessity of a product. These broader, philosophical issues about science, agriculture, and to an extent, corporate power are nevertheless important issues, especially in a society that is becoming more aware of the environmental implications of our actions (Knight, 2007). Because the current risk assessment makes no obvious attempt at addressing these wider concerns, they are often felt to be dismissed (Johnson et al., 2007; Munnichs, 2004). This can lead to hostility and misgiving towards the whole regulatory process and those who champion it (Chapter One, section 1.5.7.3-5). For a regulatory system to be successful it must inspire confidence and trust (Eden, 1998; Sjoberg, 2001), especially in cases like GM where the evaluation requires technical information and expert evaluation. Solutions to the decline in societal confidence in the risk assessment have been proposed by opponents of the current regulatory system; these have included the broadening of the regulation and the widening of expert panels (Poortinga, 2005; Wallis et al., 2005). In the paper by Johnson et al., (2007) we concurred that these concerns about regulatory scope are legitimate, however we felt that they are not valid criticisms of the risk assessment; as risk assessment needs to be scientific to enable the quantification of risk. An example we gave was that "*one would not want anyone other then an aeronautical engineer to evaluate whether a plane was safe to fly so why should it be any different for GM crops?*" (Johnson et al., 2007). We concluded that "*the scientific risk assessment is just one part of a larger evaluation of the desirability of permitting the cultivation of GM crops or any other activity judged to raise potential risks. This evaluation is risk assessment and it is here that society's concerns are addressed.*" (Johnson et al., 2007). Going back to the aeroplane analogy "*although aeroplane safety (risk assessment) should be in the hands of the aeronautical engineers, a consideration of the wider*

environmental and societal impacts of increased air travel (risk analysis) should involve a wide range of experts and stakeholders." (Johnson et al., 2007). This should be applied to GM crops and their regulation; the risk assessment is the scientific quantification of risks identified as testable endpoints that represent societal driven management goals; society should have their input at this level, not in the risk assessment stage.

Consideration should be given to the regulatory objectives the risk assessment needs to meet. Wider inclusion of stakeholders during the identification of the management goals and assessment endpoints is one way of ensuring societal concerns are met, stakeholders also need to be involved in the defining of threshold values. "*Acceptable risk cannot be determined purely scientifically, science can predict the likelihood of certain effects but non-scientific criteria must be included in the process of judging their acceptability... thus the wider societal considerations of relevance to GM crops including but not limited to, politics and economic, should play a role in driving the wider risk analysis, from the production of MG and threshold values to the communication of the risk decision*" (Johnson et al., 2007). The MG and AE in the current regulatory process need to be set out in such a way that it allows a wider range of stakeholders to identify how societal concerns about the environmental risks GM crops pose are being addressed, especially those wider concerns that do not lend themselves to a scientific evaluation. The use of broader MG, like those identified by the government (figure 6.3), could be one way of doing this, as they encompass many of the wider societal concerns the stakeholders identified in this thesis.

The second criticism, centred upon the weight given to the scientific review carried out by independent scientific experts and the political voting of Member States (Chapter Four, section 4.4.3). The question is whether the regulatory decision to approve a GM crop for deliberate release should be based purely on the scientific assessment of the risks, or on wider societal considerations. Clearly, at the moment, the regulatory objects focus purely on the science, however the votes by the Member States are political. This has implications for various stakeholders, (Chapter Four, section 4.4.3), which are summarised in table 6.3.

Table 6.3: The implications of the political voting by Member States not mirroring the science-based objectives of the regulatory process.

Consistency in regulatory approach: The industry group raised concerns relating to the way in which the scientific assessment they are required to undergo is of little value in the final regulatory decision, as Member States seem to vote politically rather then on the scientific evaluation made by EFSA. They felt there is an inconsistency in the regulatory decision with some countries always voting no and others yes; due to this, more often then not, the Member States do not come to a qualified majority either way and the decision is often referred. Referral not only ensues time delays but often further scientific assessments are required, both of which add additional costs.
Reflection on EFSA evaluation: The scientific evaluation by the independent scientists on the EFSA panel takes an extensive amount of time. For their decisions to be questioned, and in some circumstances disputed, on political rather then scientific grounds, has repercussions, as it brings the competency of the panel into question (Chapter Four, section 4.3.3.1) as well as the scope of the regulatory process.
Societal confusion about regulatory decisions: Quite often, the result of political voting by the member states is the failure to reach a qualified majority in either direction, the result of which is the deferral of the regulatory decision to grant approval to the European Commission, who more often then not base their decision on the scientific judgement made by EFSA. Often there is societal confusion, as one minute it is reported that x GM crop has been blocked approval because particular Member States voted no and then they hear it has been overruled by the Commission.

There is a clear need for the imbalance in the political voting and the scientific evaluation to be addressed. Either both are needed to be purely scientific, or these wider societal concerns considered in the political voting (implicitly) need to be identified as clear regulatory objectives. As previously mentioned, the inclusion of wider societal concerns is an issue stressed by all the stakeholders in this study which suggests a purely scientific evaluation was unacceptable. Again the proposed regulatory process illustrated in figure 6.3 would appear to address these issues; the management goals set out for future agriculture would enable the wider societal concerns about GM, like its potential to intensify agriculture etc, to be addressed within a context driven by wider societal aspirations. By requiring economic and societal assessments alongside the scientific risk assessment, the issues the Member States have with GM crops can be addressed in relation to their specific areas of concern. For example, the ethical considerations of inserting an animal gene into a plant can be discussed on its own merits rather than under the guise of objections to the scientific evaluation. The current questioning and criticism of the scientific evaluation on a political basis rather then on scientific grounds does have ramifications for society's acceptance of both the science but also those involved (Chapter One, section 1.6). If this can be reduced, then it will

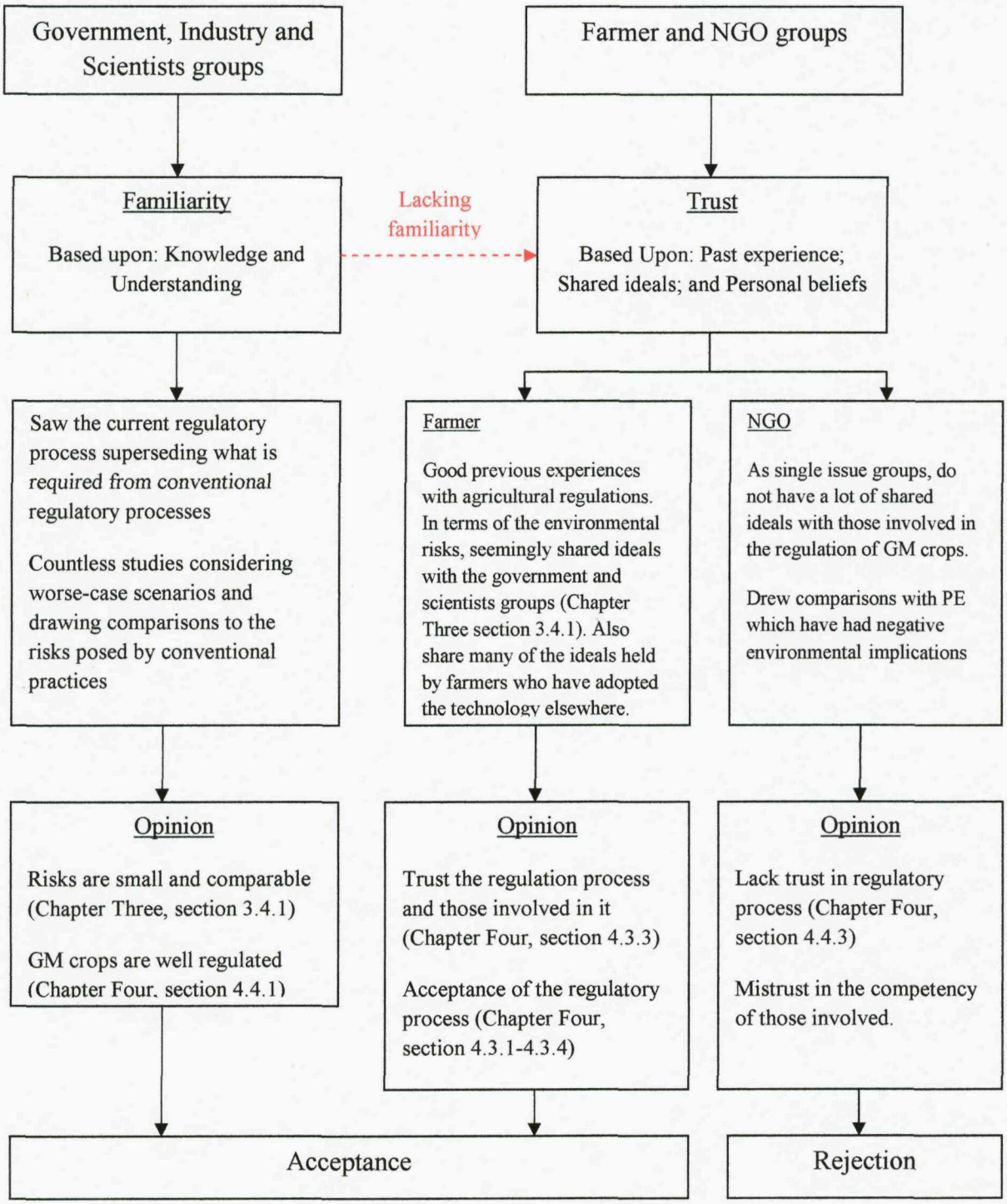
be good not only for the scientists working on and the science surrounding GM crops, but also science in general. At a time when society's trust in science, scientists, scientific regulations and therefore acceptance of innovations, is decreasing (Frewer, 2003) (Chapter One, section 1.5), those involved in science need to proactively address the causes, principally the different perceptions scientific experts and wider society have when it comes to scientific risks (Kasperson et al., 1999; Siegrist and Cvetkovich, 2000) (Chapter One, section 1.5.3). By accepting that scientific risk assessment is not on its own going to address, and thus quell, all of society's concerns and therefore identifying the need for greater inclusion of societal concerns in the regulatory assessment. The science will start to address the divide in what is deemed scientifically acceptable in terms of scientific innovation and whether the risks poses are acceptable to society; something which is required across scientific innovation.

6.2.4 The lessons to be learnt from GM for scientific innovation in general

Despite society becoming increasingly risk adverse, it is also asking more from science in terms of innovation to, for example, cure maladies, support growing global populations and improve overall qualities of life. All scientific innovations bring change; that is their nature. The changes brought will have both the beneficial intended effects but also associated unintended effects which could have negative implications. Societal acceptance of scientific innovation is depends on a number of aspects (Chapter One, section 1.6.3): familiarity (underlying knowledge and understanding) with the innovation, risk and regulations, trust in both the science and those involved and the perception of benefits and benefit spread, all play their part.

This study has illustrated how varying levels of familiarity and trust have distinguished between the various stakeholders groups' response in their acceptance of the technology and associated risks (Chapter Four section 1.6.6); this is illustrated in figure 6.5. These differences between the stakeholder groups in terms of how they form their perceptions of whether GM crops are acceptable, are equally applicable to any scientific innovation. In this study I have explained why the different groups also required such different improvements to the regulatory process (Chapter Four, section 4.3.4) and different MG and AE (Chapter Five, section 5.3). Being familiar with the regulatory process and what is required in terms of the risk assessment meant the scientists group focused on this when discussing regulatory improvements. They highlighted the need to draw comparisons with chemical risk assessment. Chemical risk assessment is more established than GM risk assessment and therefore much could be learned from the experiences gained here. This illustrated the groups' acceptance of the regulatory process, as they do not suggest any amendments to it, just improvements in the same vein. The NGO group, on the other hand, identified much broader concerns aimed at: the improvement of trust by increasing transparency in the regulatory review process, and negating aspects of the regulatory process which they had lost trust in, for example, requiring regional regulation rather than the centralised EU approach, which utilises the expertise of EFSA as the advisory body.

Figure 6.5: The roles of familiarity and trust in the stakeholder groups' acceptance and rejection of the regulatory process.



This symbolises the need to address much broader concerns if acceptance of the innovation and the regulatory process is to be improved. Currently those driving the regulatory process, and charged with improving the acceptance of it, seem only to identify with the concerns of those familiar with the process, rejecting the concerns of those who base their acceptance on trust. This is illustrated by both the recent improvements to the regulatory process, which continues on the same regulatory ilk, and the apparent dismissal of wider concerns (Chapter One, sections 1.5 and 1.6). Fundamental issues stakeholders have, which lead to their mistrust of the innovation, regulatory process, and those involved, need to be addressed if they are to be accepted.

If the issues associated with regulatory acceptance and trust is not dealt with in the case of GM crops, the concern is that the negative experiences society has with these might shape societies acceptance of future scientific innovation. In a sense, GM might become to future innovations what BSE has been to GM: a previous negative experience which undermines both the regulatory process and those involved in it (Chapter One, section 1.6). In a world where man's requirement for global resources is starting to have visibly negative implications on our planet, sustainable scientific innovation is required more than ever. Its acceptance by society cannot therefore be compromised.

6.3 Future work

This present study has raised some questions that could be explored in future studies to gain better insight into the attitudes and perceptions of stakeholders about GM crops.

A follow on study to further explore the three key findings of this study (section 6.2.1-6.2.3), would be to conduct group interviews with stakeholders. Conceptual maps could be utilised during the interviews enabling the groups to visualise the key issues in relation to each of the main findings. This method has been used in a number of studies wishing to explore complex issues with numerous and varying

stakeholders (Cannon and Leitzmann, 2005; Eden and Ackermann, 2004; Hjortso et al., 2005; Ozesmi and Ozesmi, 2003). It enables the stakeholders to visualise the issues and to consider the complex interactions between them. By doing this in groups rather than as individuals, each map will contain multiple perspectives rather than a singular one. This will be beneficial in elucidating and exploring the key issues at more depth.

Although this was out of the scope of this present study (see Chapter Two section 2.2.2), gauging public perception of the issues covered in this study, would grant good insight into the public's position on GM crops in a number of ways: firstly it would enable the key concerns of the public to be identified in relation to the issues discussed; secondly comparisons could be made between the issues identified by the public and those brought up by the stakeholder groups. Judgements could then be made as to the representativeness of the key issues raised by the other groups to the public's concerns. This could go on to explain why certain groups' positions on GM are more accepted by the public that others. The way in which the public's perception is elicited is the key question, and the use of a citizens' jury could be the answer. While direct comparisons could not be made between public concerns and those of the other stakeholder groups, due to the differences in methodological approach (see Chapter Two, section 2.2.2), the jury could be presented with the concerns of the other groups and make judgements as to the extent they felt that these concerns represented their own.

The most central finding of this study was the need to consider GM crops in the context of much wider agricultural goals, both in terms of agricultural production and environmental protection. In doing this, risk decisions can be contextualised and GM can be considered in relation to conventional agricultural production and the benefits; these goals need to be defined. This study used the goals set by the Secretary of State for the Environment, the Right Honourable David Miliband MP (figure 6.3); it would, however, be valuable to see how the stakeholders responded to these and what assessment endpoints they could define. Stakeholder inclusion in the formation of regulatory goals and assessment endpoints are crucial for

regulatory acceptance, as well as important in producing an informed assessment of the crops.

6.4 The take home message

Scientific innovation cannot be seen, or evaluated, in a vacuum, if societal concerns are to be addressed. It needs to be evaluated in a much broader context that considers the potential benefits as well as the inherent risks of the innovation itself and also the risks posed by the current practices the innovation is succeeding. Societal concerns need to be considered alongside the scientific risks if society is to accept the regulatory decisions made. This can be achieved by considering the wider implications of adopting the innovation as well as the inherent risks posed. Through the incorporation of societal concerns as management goals and the translation of these management goals into testable endpoints for the risk assessment, risk decisions can placed within the context of the initial society driven management goals. This will improve society's trust in the process, as well as their acceptance in the regulatory decision.

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