# Engineering A New Form Of Enclosure: International Convergence In Gmo Regulation

2010

Jessica Altif
*University of Central Florida*

# ENGINEERING A NEW FORM OF ENCLOSURE: INTERNATIONAL CONVERGENCE IN GMO REGULATION

by

JESSICA RACINE ALTIF
B.A. Barnard College, Columbia University, 2003

A thesis submitted in partial fulfillment of the requirements
for the degree of Master of Arts
in the Department of Political Science
in the College of Sciences
at the University of Central Florida
Orlando, FL

Spring Term
2010

# ABSTRACT

As society begins to recognize its impact on ecological systems, the belief that modern political institutions can offer a sense of control and certainty, as well as protect the health of its citizens, is increasingly questioned. In an era of uncertainty, faith in science and technology to alleviate industrial impacts on the environment is often embraced by policymakers yet questioned by the public who see the authoritative role of the sciences in the political sphere as contributing to global risk. The development of biotechnology, specifically genetically modified food, places an anthropocentric focus on resolving and/or adapting to environmental degradation, further reflecting an adherence to the dominant social paradigm to address the consequences of modernization. In order to explicate the dualism of human/nature relations inherent in biotechnology, the focus of this research provides an exploration into two competing paradigms of genetically modified organism (GMO) regulatory policy: scientific rationality and social rationality. Through a careful examination of the evolution of GMO regulation in the United States and the European Union, the precarious relationships between science and politics and progress and precaution reveal an actual convergence instead of divergence between these two actors in the international system. Although existing literature proclaims a division between the values and ethics of U.S. and EU environmental policy, the end result of this comparison in GMO regulation illustrates that in both the risk assessment and precautionary approaches, nature is still viewed as an instrument for advancing enclosure of the commons.

This work is dedicated to my parents, my brother and the countless friends and family members who have supported me in my academic pursuits. Thanks for listening all of these years.

# ACKNOWLEDGMENTS

I would like to acknowledge and thank my thesis committee members, Dr. Peter Jacques, Dr. Dwight Kiel and Dr. Phillip Pollock. Their patience and guidance throughout this process has been extremely helpful and I could not have completed this endeavor without their support. On a personal note, I would especially like to thank Dr. Peter Jacques for his constant reassurance throughout the writing process that everything would indeed be "ok." He has played the role of mentor, guidance counselor, and therapist and has been a great friend throughout this endeavor; for that I am truly thankful.

The research and writing process that goes in to the creation of a thesis can be frustrating at times. Therefore, I would also like to acknowledge Tyler Branz, Jonathan Willis, Ali Lewis and Jamie Moellentine for their friendship and support.

# TABLE OF CONTENTS

# LIST OF FIGURES

# LIST OF TABLES

# CHAPTER ONE: INTRODUCTION

As an increasingly global, interconnected society begins to recognize its impact on ecological systems, the belief that modern political institutions can continue to offer a sense of control and certainty to counteract these impacts on the environment slowly diminishes in strength. Ulrich Beck (1999) introduces the concept of world risk society to draw attention to the limited controllability of the dangers that we have created for ourselves through the industrialization process. He states that in a world risk society, "non-Western societies share with the West not only the same space and time but…the same basic challenges" (Beck 1999, p. 2). It is this idea that begins to alter what Beck sees as a bias affecting Western social science, one that places non-Western societies into the category of "traditional" or the opposite of modernity. Modern challenges for society are widespread and collective in nature. In this modern world, all are affected by new environmental hazards, both Western and non-Western nations. Global environmental issues like climate change and biodiversity loss illustrate the challenges of the risk society in that they are dangers produced by civilization and not by one specific country or group. In order to properly address these global consequences of the first modernity, Beck states that risk society demands an "opening up of the decision-making process, not only of the state but of private corporations and the sciences as well" (p. 5). A new, interdisciplinary approach that does not grant privilege to any specific form of knowledge and forces people to combine different rationality claims could help to construct an effective public sphere in which questions of value can be properly debated.

It is interesting to note that in this era of increasing uncertainty, the role of science and technology in society has either been further embraced in an attempt to adapt to global risks or has come under serious question by the public who see the authoritative role of the sciences in policy as contributing to global risk. Anthony Giddens (1990) describes industry as an entity that transforms nature and modern industry as one that is shaped by an alliance of science and technology where industrialism "becomes the main axis of the interaction of human beings with nature in the conditions of modernity" (p. 60). The development of biotechnology and genetic engineering places an anthropocentric focus on resolving environmental problems, further reflecting a faith in industrial science and technology to solve the consequences of modernization. The placement of these values on scientific discovery, reinforcing a separation between human and non-human nature, promotes a utilitarian, or purely instrumental approach to nature. This approach then accentuates the domination of humans over nature in contrast to a more integrative approach which would promote an equal standing for human and non-human actors (Latour 1999). In the realm of biotechnology and genetically modified food products, we see the implementation of this utilitarian calculus as nature is manipulated to promote human progress.

For the politics of biotechnology and genetic modification of food and plants, the separation of the individual's identity from the community in modern liberalism echoes the severance of the link between man and nature in the industrial agricultural model. Self-interest is no longer aligned with a sense of responsibility for nature. The farmer who rearranges the land for human consumption is replaced by the industrial factory model, reinforcing a dualism between humans and nature, subjects and objects (Plumwood 1993; Latour 1999). The farmer's

identity is thereby separated from the natural community through the introduction of the industrial process where nature is redefined as an 'invisible background…against which the 'foreground' achievements of reason or culture take place" (Plumwood 1993, p. 4). This division holds implications for the developing world, where private ownership of land and seed lies in direct contrast to the set of beliefs inherent in the community, in which the seed is considered part of the commons. This also bears relevance for industrialized countries as the policy challenges of the twenty-first century demand a more participatory structure for adequately assessing and resolving the risk inherent with human manipulation of the natural world, a structure based on discussion and accountability.

Ulrich Beck (1992) argues that the industrialization of agriculture represents the end of the "antithesis between nature and society" (80). Nature is no longer understood as existing "outside" of society nor society understood as existing "outside" of nature. Where 19th century ways of thinking placed nature as an object in opposition to society, Beck argues that this way of thinking has now essentially been nullified by the industrialization process itself. Bruno Latour (1999) further asserts that we need to abandon the existing social construction of "nature" and break down the barrier between subjects and objects in order to reconstruct a true public discourse to address environmental problems. The very use of the term, "nature," indicates a separation between nature and society, human and non-human, subject and object. Therefore, for Latour the solution to bringing science and democracy together lies in the deconstruction of these divisions in society and a redistribution of powers in which the social collective is extended to include non-human actors. Plumwood (1993) also discusses the problems inherent in the human/nature construction and argues that the current dualism of the human/nature relation can

explain many of the "problematic features of the West's treatment of nature which underlie the environmental crisis" (2). She emphasizes, however, that dualisms in general are a Western construction, a feature of Western thought, and not a universal concept. For Plumwood, the dualism concept is closely associated with domination and accumulation and a "modern, post-Enlightenment consciousness" (43). This Enlightenment perspective introduces a mechanistic view of the world in which nature is divided into parts to be tinkered with, infusing an instrumental value to nature instead of an intrinsic value (Merchant 1980).

Proponents of biotechnology embrace the process of "tinkering" with nature, seeing this as beneficial to the global population. These supporters of genetically modified organisms (GMOs) do not view the erosion of biodiversity as a great concern; rather, they view this as a type of collateral damage in the fight against starvation in the developing world. Thomas DeGregori, for example, states that disease-resistant varieties of crops are "essential for developing countries [and] have an untapped potential for producing food, fiber, fuel and medicine" (DeGregori 2001: p. 97). He goes on to argue that with or without the introduction of genetically modified crops, farmers around the globe will continue to embrace higher yielding or disease-resistant crop varieties, meaning that "through time, antique or traditional varieties will no longer be cultivated and in that sense, biodiversity will be further 'eroded'" (DeGregori 2001, p. 97). Indeed, DeGregori sees the main victims of a moratorium on GM crops as the poor and vulnerable population in the developing world. Dennis Avery (1995) of the Hudson Institute echoes these same sentiments in his praise for the Green Revolution and the ability of genetics to increase the potential of food production. Never once does he mention, however, the environmental impacts of genetic manipulation; Avery instead embraces a view of nature and

biotechnology more in line with the dominant social paradigm (Dunlap and Van Liere 1984) and a mechanistic perspective that Merchant (1980) associates with Enlightenment values. He states that "biotechnology can be misused – as airplanes and wheels and dynamite can be misused," going on to put forth the belief that humanity and the environment however would be much worse off without the advances of biotechnology (Avery 1995: p. 224).

By only viewing the products of biotechnology as beneficial to man and the environment (although only in an instrumental capacity), certain problems arise with the risk of ecological destruction. This type of destruction is one that can occur with the process of turning nature into a commodity for consumption. One of the largest risks in manipulating the DNA structure of plants and crops is the risk of invasiveness (Wolfenbarger and Phifer 2000). Genetic modifications can potentially "create changes that enhance an organism's ability to become an invasive species," causing unintended degradation of ecosystem functions (Wolfenbarger and Phifer 2000: p. 2088). Other risks involved in the genetic manipulation of plant DNA include non-target effects on beneficial or native organisms as well as the introduction of new viruses. An example of non-target effects of genetically modified plants is seen in the effects of Bt corn on the monarch butterfly. This version of corn produces a toxin that is not only deadly to the European corn borer but also to monarch caterpillars, an unintended consequence of genetic manipulation (Losey, Rayor and Carter 1999).

The topic of GMOs and GM food in particular represents "one of the most high profile disputes affecting environmental politics in the current era" (Toke 2007: 407). The controversy over GM products is illustrative of the previously discussed mechanistic view of the world as well as Beck's risk society theory which links the "rise of environmental concern to the

emergence of new technologies…with great potential for environmental impact" (407). The conflicts inherent in the production and distribution of genetically modified organisms (GMOs) reflect a mechanistic view of the world through the commodification of life forms and the use and manipulation of the gene pool for advancing the industrial process and favoring anthropocentric interests at the expense of the natural world. For the biotechnology industry, there is "no difference between patenting a life form and patenting an industrial product" (Coban 2004: 738). The objectification of life forms is extended through the logic of patents in which "nature" is separated from humans and made into an object to be exploited, reinforcing a dualist understanding of nature/human relations (Coban 2004; Meyer 2000). GM crops also represent a case of political power imposing specific market pressures onto farmers and consumers as the state seeks to separate "risk" from "ethics" while "reducing both realms to specialist tasks" (Levidow 2001). Contentious issues over controlling nature and society are reduced to fragments of administrative control. Technological innovation and the central role of the market are promoted as solutions to the problems of inefficiency, yet as Levidow (2001) argues, these solutions often aggravate existing insecurities.

The focus of my research in this thesis will center on explicating this dualist understanding of human/nature relations in biotechnology and examining two competing paradigms of GMO regulation: scientific rationality, embedded in a laissez-faire, market-driven atmosphere and social rationality, embedded in a social democratic emphasis on the public interest over industrial progress. In order to properly illustrate the effects of these two regulatory paradigms, this analysis will carefully examine the regulatory policies of the United States and the European Union concerning GMOs and address the possible conflicts between progress and

precautionary restraint. This research will, in turn, also highlight the precarious relationship that exists between science and politics via the regulatory process and attempt to illustrate that while these two cases are often framed as divergent in their approach to environmental issues (Eckersley 2007; Elliott 1998; Faure & Vig 2004; Isaac 2002; Lynch and Vogel 2001), both the United States and the European Union actually treat the gene pool, and by extension the natural non-human world, as an instrumental tool for advancing an enclosure of the commons. While the EU is more restrained in its approach to the genetic manipulation of nature, a capitalist structure is still embedded in this regulatory process. The conflict between the risk assessment-based approach of the United States toward biotechnology and the precautionary-based approach of the European Union presents an interesting puzzle when considered in light of the perceived universal nature of scientific discovery and progress.

- If the concept of progress in the sciences is illustrated by advances in biotechnology and genetic engineering, why do we see two separate approaches to the application of this knowledge from two equally influential actors in the international system?
    - Does a true divergence in GMO policy between these two actors exist or is their a growing trend toward convergence on genetic engineering policies?
    - Do the U.S. and EU regulatory regimes reflect a fundamental difference in values and moral acceptability of the fundamental alteration of nature or do these regulatory regimes merely reflect a difference in the political structure and hierarchy of the decision-making process?

The enclosure of the genetic commons not only has an impact on Western society but also greatly influences the trajectory of development in the Global South. The privatization of knowledge through the extension of intellectual property rights to seeds and plants challenges sovereignty of the state in the biodiversity-rich Global South and also challenges the very logic behind the progress of science itself. If knowledge in science is a common resource to be improved upon and expanded (Kuhn 1996; Lakatos 1968; Popper 1959), then the commodification of these biological resources also creates a commodification of intellectual labor and knowledge, initiating a sense of enclosure to the commons. I believe that the research undertaken in this thesis is important because it departs from the previous literature on this regulatory conflict on GMOs in the U.S. and EU by implementing an analysis of the regulatory language in both cases to illustrate an overall similarity in the end goal for both the United States and the European Union, while highlighting the subtle differences in regulatory policy that often get emphasized by those who see an impermeable divide between these two cases. Prior literature on the topic has tended to focus mainly on the intricacies of the regulatory process and the conflicts that exist between trade and biodiversity conservation, or on a larger level between the economy and the environment. My research will branch out from this existing literature by incorporating a study of the vacillating role of the knowledge creation process in environmental politics, specifically the politics of GMO regulation. In addition, part of the biotechnology literature addresses the impact of media representations of GMOs on the public sphere (Bauer 2001; Cook 2004; Ramjoue 2007), correlating the level of negative media coverage on GMOs to negative public perception of these products. My research will add to this debate on competing notions of scientific progress, the construction of knowledge and the politicization of the

sciences as a potential means to advance political and economic ends and illustrate that specific differences in regulatory language reflect more on the differences between economic and social responsibility than they do on the public's sensitivity to negative media coverage on these issues.

The framework of this comparative study of U.S. and EU regulatory processes consists of a thorough review of the literature concerning science and the knowledge creation process as well as the ever-changing role for science in policymaking. By exploring the very basics of the demarcation between science and politics, one can better understand the role of uncertainty in the knowledge creation process and the way in which scientists understand uncertainty and anomaly as part of a larger, systematic epistemology. The incorporation of the scientific process into the political arena is illustrated by a discussion of the role of science advisors in regulatory policymaking and the growing displacement of trust in scientific authority for environmental politics. A brief discussion of existing paradigmatic structures for regulatory policymaking and their emphases on economic versus social responsiveness (Isaac 2002) will follow to serve as an illustrative lens for viewing the potential divergence of GMO policies in the U.S. and EU. The third chapter explores the regulatory policies of the European Union and its adoption of a precautionary approach under the paradigm of social rationality. The language of the EU regulatory regime is examined in order to build upon a social rationality model of GMO regulation and to illustrate the emphasis human health safety and not necessarily a concern for the alteration of the ecological system. This is supplemented by an examination of public sentiment toward biotechnology and genetic engineering processes, focusing on the public's knowledge of biotechnology as well as its conceptualization of risk and moral acceptability of genetic modification in plant and food production. Chapter 4 explores the different approach to

regulating GMOs undertaken by the United States and the economic focus of its risk management framework, embedded in scientific authority and the support of industrial interests. This chapter also provides a glimpse into the public comment process as a method of fostering a greater range of public participation in the regulatory decision-making process. A comparison of the two regulatory regimes, highlighting a lack of concern with the possibility of ecological destruction at the hands of technological progress follows in order to properly show a trend toward convergence of regulatory policies, dependent upon the type of risk involved. Chapter 5 will then offer a conclusion and discussion of these two approaches to GMO regulation and the consequences of genetic engineering for global ecological concerns, a reflection on how nature is viewed in the political process.

# CHAPTER TWO: LITERATURE REVIEW

As contemporary society realizes its impact on ecological systems, the separation between nature and civilization, fact and value, begins to subside. The previous models of control, security and certainty, "so fundamental in the first modernity," slowly dissolve along with the modern conception of science (Beck, 1999, p. 2). Whether devising guidelines to differentiate between science and non-scientific practices or following Latour's (2004) abandonment of the dichotomy between nature and civilization in order to extract the core of modern science from its political shell, it is clear that the roles of science and technology have changed over time to reflect the new challenges that "industrial science" has created. Before we can address the current relationship between science, politics, and society, however, it is important to first examine the sources and limits of knowledge. The blurring of the demarcation line between science and politics has opened the door for questioning the legitimacy of scientific practice as it is used in the political arena and debating whether or not "modern science" is the only successful method for addressing new environmental challenges (Feyerabend, 1978).

For centuries, the sciences have operated in a world of subjects and objects which Latour argues are "names given to forms of representative assemblies, so that they can never bring themselves together in the same space…" (Latour, 2004, p. 72). This constant division between actors has enabled science and politics to operate on their own terms, never mixing, to address the policies and results that are infused into society. Nevertheless, the policy challenges of the twenty-first century permeate this border as "nature" has now re-entered the social world, affecting humans and society through the consequences of industrial modernization.

The realm of biotechnology illustrates a set of values and beliefs that place humanity at the center of concern and renders those considerations that do not involve the welfare of humanity as irrelevant. A clear example of these values is shown in the controversy over the effects of a transgenic corn species on the monarch butterfly. A study in May 1999 by John Losey and his colleagues (Losey, Rayor and Carter 1999) showed that a GM corn variety, called Bt corn because it contains genes from the bacterium *Bacillus thuringiensis*, produces a toxin that is not only deadly to a common pest (the European corn borer) but also to monarch caterpillars. These experiments seemed to show that Bt-corn was dangerous not only to a common pest, "but also to a species that no one had any intention of harming" (Jasanoff 2005: 108). Although the biotechnology industry succeeded in framing the scientific debate to refute any logical connection between the monarch study and commercial uses of this type of corn, many environmental NGOs and activist groups challenged the point that "science" had adequately established the safety of these products or mitigated the risks of these products to non-target species.

This manipulation of nature for the perceived benefits of efficiency and food security reinforces the dichotomy between nature and civilization and serves to further blur the demarcation line between science and politics. It has opened the door for questioning the legitimacy of scientific practice as used in its political shell and debating whether or not the knowledge produced by "modern science" is the only successful measure for addressing new environmental challenges (Feyerabend, 1978). As Bruno Latour (2004) argues, the sciences have always operated in a world of subjects and objects. This constant division between actors has enabled science and politics to operate on their own terms to address the policies and results

that are infused into society. Nevertheless, the policy challenges of the twenty-first century permeate this border as "nature" has now re-entered the social world, affecting humans and society through the consequences of industrial modernization. It now becomes imperative, according to Latour, that in order to address conflicts in society and create a true discourse in society, we must abandon nature as a socially constructed idea and embark on a reconstitution of the social world in which both humans and non-humans have a voice as actors.

Science in its politicized form is what has fueled the call for a separation of its influence from society simply for the fact that the public is no longer able to differentiate between "the sciences" and the politicized "Science."[1] Public discourse is therefore in danger of being drowned out by a reliance on scientific expert opinion. Along with this re-evaluation of the relationship between science and the political process, biotechnology and especially the creation of genetically modified crops and plants has opened the door for applying property rights to knowledge that is taken from original cultivators and turned into a commodity without paying tribute to the original growers or community, further adding to the enclosure of the genetic commons (Mushita and Thompson, 2006) and promoting at the most a modern form of imperialism (Jasanoff 2006; Newell, 2009) and at the least the growing influence of transnational corporations over the state. Nevertheless, in order to comprehend the problems inherent in privatizing knowledge for individual gain, it is important to understand the evolving theoretical debate over what defines science and how progress is measured in the scientific community.

[1] Science here is meant to illustrate the idea of scientism which privileges the use of scientific knowledge over all other ways of knowing. This type of philosophy places the methods of the natural sciences above all other means of human inquiry.

## Progress and the Creation of Knowledge through Demarcation

The works of Karl Popper and Thomas Kuhn present competing arguments to the debate on epistemology and the measurement of progress in the sciences. In two of these works, *The Logic of Scientific Discovery* and *The Structure of Scientific Revolutions*, both ends of the progress spectrum are presented and both Popper and Kuhn make convincing arguments for their interpretation of scientific discovery; revolution in the sciences is either a permanent fixture or an exceptional state. To solve the problem of demarcation between science and that which constitutes non-science, Karl Popper (1965) puts forth the idea of falsification through crucial experiments. This cycle of conjecture and refutation enables scientific progress to proceed from less general theories to more general theories in order to expand the content of knowledge. Popper's method provides a logical way of deductively rooting out "bad" theories and hypotheses that present anomalies in empirical science. Prior to Popper, inductive methodology was utilized to draw the line of demarcation between scientific and non-scientific endeavors. The deductive method of testing that is proposed in his work presents a substitution for the observation-based inductive methods and the problems that arise in the establishment of universal statements based on experience. As Popper convincingly argues at the onset of his work, "many people believe that the truth of these universal statements is 'known by experience'; yet it is clear that an account of an experience can…be only a singular statement" (Popper, 1965, p. 28). In other words, there are no pure, theory-free observations. Popper writes in opposition to the positivists who embrace inductive methods or a bottom-up approach to science, and maintain that knowledge beyond what can be observed is impossible. One can always find some evidence in support of virtually any scientific theory; however, all scientific

theories prohibit some type of occurrence, leading Popper to suggest that "whenever we try to propose a solution to a problem, we ought to try as hard as we can to overthrow our solution, rather than defend it" (p. 16). It is with this initial proposition that Popper begins to construct the crux of his argument which seeks to classify science as a problem-solving process undertaken through deductive methods of testing. The process of conceiving a new idea should always be distinguished from the methods of examining a new idea; scientific discovery should advance through a pattern of conjecture and refutation.

Methodological rules, according to Popper, are the rules of the game in empirical science and not the rules of pure logic:

> (1) The game of science is, in principle without end. He who decides one day that scientific statements do not call for any further test, and that they can be regarded as finally verified, retires from the game.
> (2) Once a hypothesis has been proposed and tested, and has proved its mettle, it may not be allowed to drop out without 'good reason.' (pp. 53-54).

These "good reasons" may include the replacement of one hypothesis (H1) by another that is described as better testable (taking the part of H1 that has not been falsified and building H2 which is able to withstand detailed and severe tests) or the falsification of one of the consequences of the original (H1) hypothesis. This second "good" reason is one that is later criticized for its erasure of those anomalies that lead to the breakdown of normal science (Kuhn, 1996; Lakatos, 1968). Anomalies are always present during the course of scientific research and

experimentation; indeed Lakatos later argues that with any conjecture that is put forth, it is known which anomalies are present that the conjecture cannot account for (Lakatos, Feyerabend, & Motterlini, 1999). While on the one hand, Popper's falsification criteria present a keen foreshadowing of the future debate on certainty and consensus in science for policy, on the other, his demarcation criterion creates ambiguities in the refutation process, thereby negating his initial proposition. For example, how do we know which anomalies are serious enough to refute a theory and which are just by-products of experimental error? One can always find anomalies in a theory just as one can always find observations that verify a theory. A similar question that has been stated by critics of falsification (Hacking, 1981; Lakatos, 1970) relates to the relationship between verification, as Popper elaborates it, and falsification: what differentiates a crucial falsifying experiment of one theory from a verifying experiment of another? The same argument that Popper had against an inductive methodology appears to infiltrate his own falsification criteria in that overthrowing one solution is also a method of defending the other. Although one can always find evidence to support virtually any scientific theory, there is also a good chance that one can find anomalies to overthrow any scientific theory; in a demarcation between good and bad theories, Popper's methodology places every theory on the bad side (see Feyerabend, 1993; Lakatos, Feyerabend, & Motterlini, 1999).

In contrast to the refutation of hypotheses through the expulsion of anomalies, Thomas Kuhn (1996) diverges from Popper's methodology and embraces the fact that anomalies exist in science; these puzzles are what allow scientists to account for a broader scope of natural phenomena. These discoveries can eventually build, over a certain amount of time, into a deconstruction of the existing paradigm and the emergence of new theories. Kuhn differentiates

between the emergence of discovery and the emergence of theory which enables him to make the case that revolution in science only occurs in exceptional times. Kuhn advocates the exploration of anomalies in research, stating that "discovery commences with the awareness of anomaly…with the recognition that nature has somehow violated…expectations" (Kuhn, 1996, pp. 52-53). However, it is only when an anomaly becomes more than just a puzzle that the transition to crisis and the emergence of theories that comprise the new paradigm structure can begin. It is interesting to point out that while Kuhn embraces the presence of anomalies in the discovery process, he laments that scientists rarely undertake the invention of alternatives in the theory-building process. He goes on to argue that science can progress rapidly when it employs the tools of the paradigm to solve the puzzles of normal-science research, so long as those tools are capable. Retooling is an "extravagance to be reserved for an occasion that demands it" (p. 76). It appears that while Kuhn emphasizes the role of anomalies in scientific discovery, the reality shows that alternate theories are not to be considered unless the traditions of normal-science research are incapable of solving the gradual build-up of puzzles during the normal-science period. It is only when the course of scientific study is delayed and the guidelines of the dominant period begin to falter that the inquiry into alternative theories arises.

The presence of normal science for Kuhn is what characterizes the majority of scientific research and progress. Normal science is defined as "research firmly based upon one or more past scientific achievements, achievements that some particular scientific community acknowledges for a time as supplying the foundation for its further practice" (p. 10). Normal science is practiced within the dominant paradigm, meaning that whatever puzzles or problems arise during normal research carry with them the conjectures of the dominant paradigm. When

normal, puzzle-solving, science goes astray, investigations then commence that lead the profession to a new set of commitments. Scientific revolutions, on the other hand, are "tradition-shattering complements to the tradition bound activity of normal science" (p. 6). This type of extraordinary science emerges only on special occasions that are prepared by the advance of normal science. Kuhn looks to the examples of Copernicus, Newton, Lavoisier and Einstein to illustrate major turning points in science and show how these major shifts evolved from normal science practice. Each one of these turning points required that the scientific community reject one conventional scientific theory and replace it with an incompatible alternative; in other words, there was a large enough consensus that the path of research needed to change to incorporate either new tools for research or a new way of thinking about a research field. Each turning point also produced a shift in the problems available for scientific scrutiny, thus widening the content of knowledge.

What is important to note in Kuhn's work is the role that the scientific community plays in deciding what advances knowledge and what does not. This type of "elite authoritarianism," as argued by Imre Lakatos (Lakatos, Feyerabend, & Motterlini, 1999), claims that the demarcation criteria in determining the composition of science is "inarticulable" and that scientific revolutions are always progressive and always lead to an increase in knowledge. While Kuhn describes the progressive nature of paradigms, it is difficult to see exactly how one can compare two paradigms in order to determine if a revolution is progressive. Responses to Kuhn's work (Lakatos & Musgrave, 1970; Phillips, 1973) have questioned the varying definitions of the term "paradigm" along with Kuhn's explanation, or lack thereof, as to how the scientific community actually measures progress through paradigm shifts. If "the normal-

scientific tradition that emerges from a scientific revolution is…incommensurable with that which has gone before," (Kuhn, 1996, p. 103), then how does one conceptualize progress in this manner? The traditional cumulative nature of science that Popper does actually acknowledge in his cycle of conjecture and refutation lies in direct contrast to Kuhn's concept of scientific progress. The objectivity that scientists had embraced in the past is now subjugated to the beliefs of a particular community of participants, solidified by the dominant paradigm, which are then translated into fact and knowledge. Instead of a dividing line between fact and interpretation, these two concepts congeal under the dominant paradigm; using Kuhn's most elementary definitions of "normal-science" and "paradigm," including the role that paradigms play in the education of scientists, the argument that a scientific community determines what is progress and what is not does receive valid support. It is the study of paradigms that, according to Kuhn, "mainly prepares the student for membership in the particular scientific community with which he will later practice" (p. 11). This commitment and the consensus that is produced by the study of paradigms is what permit the continuation of the research tradition. Nevertheless, the social construction of beliefs inherent in the structure of paradigms presents a problem for retaining any type of core scientific knowledge.

## Paradigms or Research Programmes? Arguments against a Constrictive Methodology

As previously discussed, Kuhn emphasizes the importance of anomalies in the discovery process; however, his arguments on the constitution of scientific progress lack the firm foundation that is found in Popper's notion of a cumulative science based on a gradual

progression of "more fit" theories. With Kuhn, the incommensurability of paradigms acts as a barrier to the normal Popperian concept of progress exemplified through a sophisticated brand of falsification. To address and build upon this division, Imre Lakatos (1968, 1970) proposes a methodology of scientific research programmes in which he borrows from Popper's falsification criteria and Kuhn's theory of scientific revolution in an attempt to provide a comprehensive demarcation between what is science and what is not, that which has more truth content and that which has less. While Lakatos agrees with Popper on the problems of induction, he is largely critical of the conjecture-refutation cycle that comprises the falsification method. Instead of focusing on isolated theories in which one proceeds by conjecture and refutation from less general theories to more general theories in order to expand the content of knowledge, Lakatos argues that one should focus on a series of theories, or research programme. He rejects Popper's view of the history of science and questions Popper's use of anomalies in the refutation process, specifically asking how one differentiates from a serious anomaly that leads to refutation and a minor anomaly that does not. Lakatos provides the example of Bohr's theory in his criticism of Popper's naïve falsification, arguing that even though Bohr had inconsistencies in the first form of his theory, he did not drop it altogether. For Lakatos, true scientific revolutions "consist of one research programme superseding…another" (Lakatos, 1970, p. 115). A research programme is successful if it leads to a progressive problem-shift; a programme is unsuccessful if it leads to a degenerating problem-shift.

An important contribution that Lakatos lends to the ongoing epistemological debate is in his statement that research programmes can be progressive or *degenerating*; that is to say, might is not necessarily right. In this proposition, he attempts to use Popperian methodology to show

that there is "good, progressive normal science and that there is bad, degenerating normal science" (Lakatos, 1968, p. 167). Kuhn only sees the progressive nature of science; Lakatos adds the degenerating aspect. In between the "revolution in permanence" and the belief that "revolution is exceptional," Lakatos provides a type of middle ground that incorporates aspects of both Popper and Kuhn. His programme is one in which falsifications are recorded but not necessarily acted upon and the conventionally accepted "hard core" of science is protected by a belt of auxiliary hypotheses (1968, p. 150). It is only when the driving forces of the positive heuristic, which defines problems and constructs the belt of auxiliary hypotheses, weaken that anomalies are examined more closely. One important difference between Lakatos's methodology and previous arguments rests with the timing of revolution in science. Lakatos argues throughout his writings that no experiment is crucial at the time it is performed; an experiment can only be seen as crucial once one research programme has overtaken another. The use of Newton's gravitational theory provides a reinforcement of this proposition as well as an example of Lakatos' criticism of Popper's "naïve falsificationism." When the theory of gravity was first produced, it was "submerged in an ocean of anomalies" (1968, p. 169). Nevertheless, Newton was able to turn these anomalies into corroborating instances, representing a progressive theoretical shift that increased empirical content. Popper's falsification criteria would have discarded this theory at the sight of the first anomaly.

Lakatos borrows from Popper's more "sophisticated" falsification in order to construct his methodology of research programmes. This revised method of falsification takes the scientist away from making decisions based on isolated theories and advocates for a consideration of one theory in the company of others. With his integrated methodology, Lakatos also solves Kuhn's

problem of paradigm incommensurability by altering the structure of research to incorporate a hard core of scientific research which maintains its integrity and an auxiliary hypothesis belt which can slowly change to accommodate the growing presence of anomalies. In addition, Lakatos provides criteria for progress and stagnation in scientific research through his development of problem-shifts and an alteration of Popper's "sophisticated" falsification criteria. A series of theories is considered progressive if each new theory "has some excess empirical content over its predecessor, that is, if it predicts some novel, hitherto unexpected fact" (Phillips, 1973, p. 20). Lakatos very carefully attempts improve upon Popper's falsification criteria, which he argues is capable of defining the progressive or degenerating nature of scientific research programmes, and Kuhn's theory of paradigms.

The weakness of Lakatos's methodology, however, presents itself in almost the same manner exhibited by Popper's original falsification criteria. With Lakatos' progressive and degenerating programmes, how do we know how much time to give a programme that is degenerating before eliminating it? What if the programme looks like it is degenerating but then turns out to be progressive? Feyerabend (1993) and Kuhn both focus on this aspect of Lakatos's proposed methodology in their criticisms, offering valid points against certain propositions that Lakatos presents. Throughout his description of research programmes, Lakatos completely ignores the decisions that influence what is termed "corroborative" or "progressive," all of which are influenced by commitments shared by the community, the paradigm structure that Kuhn presents and that which is seen as "ideological commitments" by Feyerabend (1978) in his essays on science and society. Both Kuhn and Feyerabend tend to question the "rational aspect" of science whereas Popper and Lakatos both see the growth of knowledge as taking place in what

Popper describes as the "third world…the world of articulated knowledge which is independent of knowing subjects" (Phillips, 1973, p. 21). Unfortunately, this belief of a rational division of worlds does not aid the scientists who work in the first two worlds and fails to incorporate a more democratic process into decision-making. This failure becomes increasingly important as political scientists, sociologists and historians of science begin to examine the relationship between science and politics and the fluctuating levels of influence that science has on society.

The view of science as a progressive process that builds upon previous theories is an idea that permeates throughout much of the history and philosophy of science. While Lakatos contributes to this literature by adding a degenerating aspect to scientific research, Paul Feyerabend departs even further from these previous efforts and states that progress has to be measured by the growth of knowledge that includes an examination of many alternatives; Western science alone cannot, and should not, account for all scientific progress. Feyerabend argues that there are no set of methodological rules that all scientists use; elements that constitute the sciences "have no common structure…procedures that paid off in the past may create havoc when imposed on the future" (Feyerabend, 1993, p. 1). He is not arguing against the use of *any* methodology in science; instead, Feyerabend attempts to show that there is not a *standard* methodology to science. Progress occurs through the adoption of a pluralistic methodology that allows for the creativity of scientists, a type of epistemological anarchism. Science is "our creation, not our sovereign; it should be the slave of our whims and not the tyrant of our wishes" (Lakatos, Feyerabend, & Motterlini, 1999, p. 118). According to Feyerabend's (1993) thesis, the problem with Popper's falsification criteria, Kuhn's paradigms and Lakatos's research programmes is that they all try to simplify scientific achievements and success. Knowledge

creation is a disorderly process that illustrates the unevenness of scientific development. There is never a solid line of demarcation that is drawn between scientific and non-scientific pursuits.

In order to support his thesis, Feyerabend uses historical examples to show that the success of science should not be used to usher in a standardization of methodology to treat unsolved problems. The central example used here is Galileo's defense of the Copernican theory against the tower argument, a method used by followers of Aristotelian logic to challenge the theory of the earth's rotation. Feyerabend is able to show the benefit of counter-inductive methods and ad hoc adjustments to protect a new theory from a potential falsifying instance. This example also aids his criticism of Popper by showing that ad hoc adjustments can actually have a positive effect on science. Facts, according to Feyerabend (1993), contain ideological components that are "highly suspicious…first, because of their age and obscure origin…secondly, because their very nature protects them…from critical examination" (p. 62). Along the same line of argument that Kuhn (1996) offers in his section on the importance of anomalies in science, Feyerabend's criticism of Popperian methodology states that when a contradiction arises between a new theory and a collection of established facts, the best procedure is to discover the reason for the contradiction, not simply abandon the theory. The quality of new theories should not be judged by a comparison to previously known facts, something which is referred to as the consistency condition. This type of comparison is unreasonable because it "preserves the older theory, and not the better theory" (Feyerabend, 1993, p. 24). This condition eliminates alternatives and, therefore, does not increase the content of knowledge. Through these historical examples, Feyerabend is also able to suggest that progress occurs in the sciences most often through the violation of existing rules.

While Feyerabend's advocacy for a pluralistic methodology represents a radical departure from the philosophy of science, his criticisms of "normal-science" and falsification are well argued and his brand of epistemological anarchism is presented in a clear and concise manner which makes his argument easier to follow when compared with the ambiguous statements found in the research programme methodology of Imre Lakatos (1968; , 1970). The methodology of scientific research programmes attempts to open up the rationalist restrictions of normal science while simultaneously holding on to a rationalist framework for progress in the sciences. While the concept of a research programme attempts to bridge the divide between a coherent, standard methodology and a more pluralistic methodology, Feyerabend's theses on epistemological anarchism provide a way out of the restrictive mold of modern scientific research that previous historians and philosophers of science have tried to overcome (Feyerabend, 1993; Lakatos, Feyerabend, & Motterlini, 1999). Nevertheless, Feyerabend never provides a way to eliminate those theories that simply do not qualify as "good science." Since there are no mechanisms for deciding what is to be selected and what is to be rejected in science, every alternative must be addressed at all times. This would seem to inhibit the progress of science, leading to a reduction of knowledge instead of an expansion. Although it seems the intention of Feyerabend to reject the banality of normal scientific procedure, it is precisely within Kuhn's period of normal science research that a series of alternatives can be discussed and either conceptually assimilated or used to spark an eventual paradigm shift. This restrictive practice is what enables change to occur, ensuring that a consensus is established before progressing along a new path. Nowhere in Feyerabend's "method" is consensus addressed. Perhaps it is because of this type of consensus, forged by a series of ideological commitments existent within the dominant paradigm, that

modern science has retained an elevated position in political decision-making, a development that Feyerabend fears will have a negative effect on democratic practice. With the uncertainty and anomalies inherent in scientific discovery, the question of where to place science in the policymaking process gains greater importance. Should science be separate from society or is there a way for scientific expertise to play a role in democracy without sacrificing both sound methodological practice and democratic values?

Science in its politicized form is what Feyerabend attacks when he argues for a separation of the influence of "science" from society. He views expert scientific opinion as exemplary of the perversion of unanimity in the scientific community where "dissenters are suppressed or remain silent to preserve the reputation of science as a source of trustworthy and almost infallible knowledge" (Feyerabend, 1978: 88). Bruno Latour's solution to this problem, of course, is a redefinition of political ecology, one in which the sciences are one of several skills that inform the collective of human and non-human actors. Science is divided here between the politicized forms lamented by Feyerabend that encapsulates the "ideal of the transportation of information without discussion or deformation" and the second meaning of science that refers to the ability to gain access to non-human entities through experiments and calculations (Latour, 1999: 258). The role of scientists is not to make or manage these entitites but to use this access to enrich their ontology. Latour does not see a division where one side dominates the other; for modern society to appropriately address ecological conflicts, a wider participatory base is needed that includes a plurality of alternative ways of knowing in order to advance the best solution.

Stemming from Feyerabend's advancement of a more pluralistic methodology, Vandana Shiva (1997) sees science as a pluralistic enterprise that refers to different ways of knowing.

Scientific claims arising from the commitment of a specialized community of scientists as described by Kuhn fail to leave any criteria "to distinguish the theoretical claims of indigenous non-Western sciences from those of modern Western science" (8). Science is supposed to be an expression of human creativity, both individual and collective and not an expression of an elite community of scientists. Shiva views the advancement of modern Western scientific practice into non-Western cultures as a result of Western cultural and economic hegemony as opposed to cultural neutrality. This dominant model of scientific knowledge is rendered inadequate by its reductionist and fragmented characteristics that "are not equipped to take the complexity of interrelationships in nature fully into account" (8). Society's progression towards a "monoculture of knowledge" ignores the ecologically-based indigenous knowledge systems and creativity these systems bring to issues pertaining to the life sciences; intellectual diversity is slowly eroding which presents a contrasting view to Latour's reconstruction of political ecology as a way to engage public discourse. Shiva's unique perspective lends weight to the benefits of a plurality of methods to advance both biodiversity and the intellectual diversity of the sciences.

## Science, Knowledge Creation and Policy

Decision-makers who are charged with protecting the environment and public health rely on scientific and technical expertise to inform their decisions on policy. The assumption that science is somehow superior to other methods has allowed this discipline to gain a privileged seat in the policymaking arena. Maintaining the right balance between scientific discovery and the public interest, however, is an arduous task when theory has to be translated into policy

prescription. The theoretical literature focusing on science and democracy tends to emphasize the social construction of science and how scientific communities, as well as institutions themselves, can influence knowledge creation and subsequently influence democratic practice. Part of this literature also examines the changing role for scientists in light of current global environmental challenges that incorporate a higher level of uncertainty and unpredictability. By ushering in a new place for science in politics, it is possible that the puzzle-solving activities involved in addressing these new global challenges will pave the road for a more democratic structure to the sciences and provide a baseline for a more collective approach to solving environmental problems.

The area of government where science, technology and society converge is in the regulatory process, primarily in health and environmental policy. The relationship between the knowledge created by the scientific community and the political agencies that must transform that knowledge into policy is often plagued with disagreement. Jasanoff (1990) provides an excellent window into the politics of scientific advice by advancing a critique of the technocratic and democratic paradigms for managing the use of science in the regulatory process. She argues that neither approach "takes adequate account of the nature of science or politics," (Jasanoff, 1990, p. vii). Jasanoff uses a range of cases from the herbicide 2,4,5-T to emissions standards to illustrate the drawbacks of the democratic model which relies on judicial review and open administration. She states that the conceptual model developed to deal with technical disputes, which she terms the "science policy paradigm," failed because "it created a politically unstable mix of too much administrative discretion combined with too little judicial deference" (Jasanoff, 1990, p. 40). The push for greater public debate over the legitimacy of science decisions creates

too much of an altered structure of scientific authority among actors in the regulatory process to be effective. The technocratic model of science advice is also rejected due to the disparity between "regulatory science" and "research science." As Jasanoff effectively argues, the peer review process is most successful at forging consensus among scientists of similar training and outlook, those subscribing to the same Kuhnian paradigm. The belief that this process can translate to a multidisciplinary environment under pressure of regulatory deadlines is tenuous at best. These criticisms of the technocratic and democratic models provide much needed insight into the difficulty of applying the methodology and beliefs of "research science" to the public policy forum.

To support the case for a more realistic account of the role of scientific expertise in policy decision, Jasanoff draws empirical data from a close examination of the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) and the science advisory committees affiliated with these agencies. The evolution of the relationship between the Clean Air Scientific Advisory Committee (CASAC) and the EPA is an example of "mutual accommodation between scientists and policymakers" that provides a model for other Science Advisory Board committees. To examine standards for air pollution control, "the basic boundary between science and policy had to be carefully readjusted so that neither EPA nor CASAC could claim exclusive jurisdiction over key elements of the standards setting process" (Jasanoff, 1990, p. 101). While the EPA works on readjusting boundary lines in its advisory process, most of the FDA's advisory processes involve the blurring of these lines between science and policy. Expert advisors are allowed to examine evidence from nonscientists as well as scientists and advisory proceedings are "structured in ways that leave the line of demarcation between FDA's decision-

making authority and that of its scientific advisors ill-defined" (Jasanoff, 1990, p. 178). As Jasanoff points out, however, the approach used by the FDA works well at reducing conflict over the interpretation of regulatory science, lending support to her earlier proposition that in order to prove genuinely useful, "proposals to improve the use of science in the regulatory process have to be informed by an accurate knowledge of the internal dynamics of both science and regulation" (Jasanoff, 1990, p. 17). What Jasanoff is successful at showing is that scientific advising is not as clear-cut as simply restricting the process to technical issues or, even worse, denying that "values" are irrelevant to the process; the clear boundary line between facts and values no longer exists. Negotiation among and between scientists and the public is viewed here as one of the keys to success of the advisory process and a tactic that promises to remain important as political agencies tasked with environmental and public health policymaking continue to seek consultation from the scientific community. In the area of biotechnology, Jasanoff (2005) rearticulates her idea that contemporary societies are constituted as knowledge societies and important aspects of political action tend to "cluster around the ways in which knowledge is generated, disputed, and used to underwrite collective decision" (6). She further argues that the concepts of risk and safety, ideas of causation and blame and crucially for biotechnology the boundary between "nature" and "culture" have been shown to reflect deep-seated social assumptions that rob them of universal validity. It is clear in her work that while scientists may claim objectivity, policymakers carry on business through careful boundary maintenance, "favoring some voices and viewpoints at others' expense" (14). It is here that the ideological components and politicization of science that Feyerabend saw as detrimental for society may provide a greater force than actual scientific objectivity. The case of GMOs,

especially in agricultural trade policy between developing and developed states, illustrates the competing interests that policymakers must take into account when developing a framework for balancing the relationship between political discussion and participation and scientific progress.

Further blurring the lines of demarcation between a) the science of Kuhn and Popper in which scientific procedures and discoveries occur in an objective, rule-oriented framework, and b) the science of environmental policy and risk, Jane Lubchenco (1998) and Funtowicz and Ravetz (1990; , 1993) both address a type of "post-normal" age in which unprecedented environmental and social changes reveal an increasing amount of uncertainty and unpredictability. These new issues of the post-normal age differ from traditional scientific problems in that they are global in scale, have a long-term impact, and the quantitative data on their effects is largely inadequate. Funtowicz and Ravetz argue that the skills required for managing these new challenges have largely been neglected due to the reliance on the "correctness" of scientific assertions and the belief that the language of science is always precise. This belief, however, "has become recognized as unrealistic and counterproductive…our culture invests a quality of real truth in numbers, analogous to the way in which other cultures believe in the magical powers of names" (Funtowicz & Ravetz, 1990, pp. 9-10). In other words, society's faith in statistical data opens a trap in which the quantity of data presented is placed above the quality of data.

Quantitative data is capable of seriously misleading those who consume it; the shroud of certainty that covers statistical data usually makes it more difficult for scientists to advise policymakers on issues like climate change which carry with them uncertain predictions based on computer and mathematical models. A concern with quality control in the sciences leads

Funtowicz and Ravetz to propose a different approach for assessing uncertainty and quality in a variety of policy issues. The approach of Numeral, Unit, Spread, Assessment, and Pedigree (NUSAP) moves from a more quantitative to a more qualitative aspect of the information examined. This approach incorporates both quantitative and qualitative layers of analysis for investigating levels of uncertainty and attempts to provide an empirical method for assessing the correct solution for each issue. While this notational scheme provides a new way to approach policy issues of uncertainty, especially in the realms of pollution and climate change, it also seems to oversimplify the complex nature of these issues. The more interesting part of their argument rests in their proposal for a change "in the symbolic and social roles for science" (Funtowicz & Ravetz, 1990, p. 2). The authors assert through the example of the "Ch-Ch Syndrome," coined from the disasters of Chernobyl and the Challenger space shuttle that quality assurance can no longer be taken for granted. The NUSAP approach "embodies the principle that uncertainty cannot be banished from science; but that good quality of information depends on good management of its uncertainties" (Funtowicz & Ravetz, 1993, p. 740). A new role for scientists needs to include the use of a proper methodology to manage uncertainty in order to provide the best quality of information.

The argument put forth by Funtowicz and Ravetz in *Science for the Post-Normal Age* presents a more convincing case as it consolidates their previous work into a clear and concise proposal for how to alter current scientific methodology in order to better address global environmental risks. The extension of the peer community to include all stakeholders in an issue opens up the possibilities for "enriching the processes of scientific investigation" (Funtowicz & Ravetz, 1993, p. 753). Nevertheless, it is clear that the authors would not advocate the use of

alternative methods in all areas of science; it is only in post-normal science, where either systems uncertainties or decision stakes are high, that they appear to support an extension of the peer community. It would seem, however, that once the community has been extended to incorporate all stakeholders, then these participants should also remain for every discussion, even when uncertainty and the decision stakes involved are lower. If new policy challenges stem from a growing sense of uncertainty, is it possible to divide concerns into separate groups of core science, applied science, and post-normal science? The designation of "post-normal" science would appear to be more of an all-encompassing category for contemporary environmental problems, not just merely one category among many.

In her discussion of a new social contract for science, Jane Lubchenco also envisions a new type of science for handling global environmental challenges. Lubchenco, however, focuses mainly on the scientific community itself and not on the incorporation of additional stakeholders in the decision-making process. This seems to imply that the scientific community can still fix the problems of society so long as scientists acknowledge society's changing needs. Posing the question of whether or not the same scientific enterprise that has met past challenges is prepared to meet the new challenges that lie in the future, Lubchenco makes the case that the current enterprise of science is, in fact, not prepared to meet the challenges that lie ahead. She asserts that the new issues we now face "have not been fully appreciated nor properly acknowledged by the community of scientists whose responsibility it is, and will be, to meet them (Lubchenco, 1998, p. 491). The main conclusions that Lubchenco draws are that the roles of science have not changed; the needs of society have altered dramatically and the growing human dominance over the planet requires new types of knowledge and applications from science. Knowledge to inform

policy and management decisions is seen as one of the most important applications of modern science; however, Lubchenco's argument appears to reinforce the divide between the scientific community and society instead of creating an open space for collective discourse on society's needs. For instance, the new contract is predicated on the assumptions that scientists "will address the most urgent needs of society…communicate their knowledge and understanding in order to inform decisions of individuals and institutions…and exercise good judgment" (Lubchenco, 1998, p. 495).

Although recognizing the presence of uncertainty and the seriousness of today's environmental problems, Lubchenco reinforces Latour's (2004) disconcerting criticism that modern scientists attempt to serve as a bridge between reality and the Cave. Scientists address society's needs in proportion to their importance and then communicate their knowledge to individuals and institutions. Yet the question that remains is who decides which needs are important? Is it the scientific community itself, relating back to Kuhn's assertion that science follows the path of paradigms? Or is the direction of scientific research decided in the political realm? In order to truly address these uncertain environmental and social challenges, perhaps it is necessary to have a broader community of participants included in the creation and dissemination of knowledge.

## A Reassessment of Science and its Place in Society

The bond forged between science and democracy in a growing age of uncertainty is reflective of the separation between nature and civilization. As evidenced in the literature,

scientists are still viewed by many as managers of environmental uncertainties and, in their capacity as advisors, producers of knowledge about the world. Until we dissociate the sciences from "Science," or the "politicization of the sciences through epistemology," we will always be in the Cave looking at shadows on the wall while scientists perform the task of reporting back about the state of the world (Latour, 2004, p. 10). While Lubchenco (1998) asserts that it is the needs of society that have changed and not the roles of scientists, Bruno Latour argues that in order to even recognize these needs, the place of scientists in society must be reconstructed. With the goal of bringing the sciences back in to democracy, Latour offers a way to remedy the problematic placement of science in society. In order to accomplish this task, Latour proposes a reorganization of social functions that emphasizes the collective associations of participants in which each of the disciplines (scientists, economists, politicians, and moralists) has a role to play.

The current practice of political ecology, as presented by Latour, reflects a socially constructive view of nature that can only be known through the sciences. As Latour states, science cannot remain a mirror of the world, but must be repositioned to the very core. He argues that "nature is the chief obstacle that has always hampered the development of public discourse" (Latour, 2004, p. 9). Up until now, a true political ecology has not existed; the two words have simply been placed together without rethinking the true meanings behind them. In order to reconstruct discourse among actors and construct a collective that extends to both human and non-human actors, we must step out of the Cave and discard "political epistemology" so that a true discourse among actors may exist. We must abandon nature as a socially constructed idea

and embark upon a reconstitution of the social world in which both humans and non-humans have a voice as actors.

Science in its politicized form is what has fueled the call for a separation of its influence from society. Feyerabend views expert scientific opinion as exemplary of the perversion of unanimity in the scientific community where "dissenters are suppressed or remain silent to preserve the reputation of science as a source of trustworthy and almost infallible knowledge" (Feyerabend, 1978, p. 88). The problem, however, with this argument is that "the sciences" and the politicized "Science" are viewed as one and the same; the public can no longer differentiate between the two and therefore public discourse is in danger of being drowned out by a reliance on scientific expert opinions. Latour, on the other hand, improves upon this argument, claiming that the only solution to this problem is through a redefined political ecology, in which the sciences are one of several skills that inform the collective of human and non-human actors. Science is divided here between the politicized forms lamented by Feyerabend that encapsulates the "ideal of the transportation of information without discussion or deformation" (Latour, 1999, p. 258) and the second meaning of science that refers to the ability to gain access to non-human entities through experiments and calculations. The role of the scientist is not to make or manage these entities but to use this access to enrich their ontology. Without an extension of the collective to include non-humans, science cannot advance; puzzles and controversies are required by the science that remains after liberation from the political.

## Scientific Rationality and Precaution

Building from the literature on risk and uncertainty in science policymaking, it is clear to see that there is not always a clear separation of subject and object, self and "other" when the scientific process is incorporated into the public sphere. The issue of regulating biotechnology presents a challenging problem because "technological innovation, while promising opportunity, has always encountered public anxiety about its risks" (Isaac 2002: p. 125). While certain actors may see progress in the sciences as creating greater certainty for policymaking, still others view a blind faith in science and technology as increasing the amount of uncertainty in the modern world system (Beck 1999). In order to address the uncertainty and potential unintended consequences of technological innovation applied to environmental concerns, a framework of risk assessment is often employed, weighing the costs and benefits of new policies and employing empirical definitions of safety, "distilling risk down to a mechanistic causal-consequence model" (Isaac 2002: p. 129). Risk assessment places a large amount of faith in science and technology to provide accurate models of harm in increasingly complex ecological systems. This type of assessment is viewed in the U.S. regulatory arena as "sound science," in which decisions are made on the basis of what can be quantified, without considering what is unknown or cannot be measured" (Tickner and Raffensperger 2001: p. 14). Scientific rationality in this case is reflective of the domination of industrial and economic interests at the expense of social responsiveness.

Diverging from the viewpoint that science can resolve the issues of modernization, a precautionary approach advocates "taking precautionary action before scientific certainty of cause and effect" (Tickner and Raffensperger 2001: p. 4). This type of approach recognizes

uncertainty and admits that there are limitations to the scientific process. As a risk management tool, the precautionary approach focuses more on speculative risks, "for which a risk assessment cannot be performed" (Isaac 2002: p. 143). This type of risk management tool is also much more inclusive of public concerns and perceptions and is not confined to an elite group of scientists to determine what kind of risk is acceptable in the name of progress. The regulatory policies of GM food in the United States and the European Union reflect the differences in these two approaches to accounting for uncertainty in science and technological innovation. Nevertheless, while the approaches to regulating GM food may differ across the Atlantic Ocean, it is clear that both approaches still place an instrumental value on nature and are more concerned with the effects of this new technology on human health and industrial productivity instead of harboring a concern for what it means to manipulate nature and bypass the process of evolution.

## The Case Study Approach

To illustrate the different interpretations of scientific knowledge and uncertainty in the political sphere, a study of the United States' and the European Union's regulatory policies concerning GMOs is employed here. By examining the subtle differences in each case's approach to the genetic manipulation of nature, one can see the vacillation of authority between science and the public in environmental policymaking. While the United States initially employed a precautionary approach to environmental matters, the approach to new technology and its products was drastically altered during the period of deregulation in the 1980s. For example, in 1974 a group of scientists in the United States "called for a temporary moratorium

on research involving genetic engineering," however this initial support for precautionary policy was soon undermined once the commercial potential of biotechnology was realized (Lynch and Vogel 2001). The European Union, on the other hand, reflects a more social democratic approach to environmental regulation in which public participation and concern is included in the risk management process. Nevertheless, while the EU's precautionary approach to GMO regulation emphasizes a greater concern for its citizens' health, the regulatory policy employed still ignores the fact that by modifying these organisms, scientists are manipulating the very basis of life and treating the gene pool as a tool for humanity's progress. It is also interesting to note that it is only in food production that the EU diverges from the U.S. on genetic modification; the use of this technology in medicine does not create the controversy between these two actors that the use of this technology in food production does. This implies a potential convergence of policy and homogenization of political goals that has previously been neglected in the prior literature.

To provide a careful analysis of the regulatory policies concerning GMOs in these two cases, the research employed will be restricted to the years 1996-2003. In 1996, the first exports of GM products from the United States were shipped to the European Union, sparking an interest in the public sphere over what type of risk was involved in the modification of food products. It was also during this year that the United Kingdom experienced the BSE crisis, calling into question the faith in science and technology to solve the problems of modernity (Beck 1999). It was during this crisis that the public's faith in scientific authority was called into question as the same government that had told the public that "beef was safe" later admitted to "failings in the scientific advisory system that delayed measures that might have reduced the size of Britain's

BSE epidemic, or limited the amount of potentially infective material entering the human food chain" (Aldhous 2000). This time period also covers the adoption by the EU of the Cartagena Protocol on Biosafety which was implemented to protect biodiversity from the potential risks resulting from biotechnology. The Cartagena Protocol references a precautionary approach to the biotechnology process as advocated by Principle 15 of the Rio Declaration on Environment and Development, stating that "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism (LMO) on biodiversity…shall not prevent a Party of import from taking a decision…in order to avoid or minimize such potential adverse effects" (Article 10.6, Cartagena Protocol on Biosafety). Each case study examined will explain in depth the changes in regulatory policy concerning GMOs, reflecting a scientific or social rationality toward policymaking as well as address the differences in public opinion and media coverage. The research will not only illustrate the subtle differences in conceptions of science and technology for policy but to also show the convergence of ways of thinking about nature as both approaches still emphasize the nature/civilization dualism.

# CHAPTER THREE: EUROPEAN UNION REGULATION OF GENETICALLY MODIFIED ORGANISMS

The European Union views GMOs as non-natural constructions that necessitate a separate law regulating these organisms compared to natural plants. The 1990 Directive (90/220) on the "Deliberate Release into the Environment of Genetically Modified Organisms" states that GMOs are "organisms in which the genetic material has been altered in such a way that does not occur naturally by mating and/or natural recombination" (Official Journal of the European Communities 1990: p. 15). Most policy debates in the European Union have been framed in terms of potential risks to human health, however, and not necessarily in terms of the effects of genetic manipulation on the environment. This presents an interesting development because it places the precautionary approach of EU regulation in the same arena as the risk assessment approach of U.S. regulation in that both regimes advocate an instrumental view of nature, a continuation of the nature/civilization divide. Many Europeans' concerns about advances in biotechnology actually seem to stem from a widespread lack of trust in democratic institutions and not necessarily in the science behind these innovations (Europe Ambivalent on Biotechnology 1997). Nevertheless, the regulatory regime employed by the European Union does offer a more restrained approach to advancing the industrialization and commodification of nature, even if the values behind this approach are utilitarian in their construction.

## The Precautionary Principle and the EU Regulatory Regime

The European approach to GMO regulation attempts to achieve a balance between progress and precaution. Although normally related to hazardous chemicals and pollution (Quijano 2003; Tickner 2003), several essential elements found in the precautionary principle also apply to scientific advances in biotechnology. The principles of prevention, reverse onus, and the view of uncertainty as a threat and not a benefit are all applicable to the regulatory policy of GMOs. The precautionary principle is not, in fact, unscientific or reflective of a radical ideology (contra DeGregori 2001); the evaluation process of precaution actually incorporates a greater amount of scientific evidence than a risk assessment approach which only takes into account hypothetical risks and not those of a speculative nature. The "intellectual linchpin" of the EU position on GM product regulation is in fact based on the presence of scientific uncertainty; because the risks of GM food products are imperfectly known, the EU position is often that it is "impossible to attach science-based probabilities to [the risks]" and that "scientific risk-based assessments of GMOs is not currently possible" (Chambers and Melkonyan 2007: p. 520). The scientific uncertainty alluded to in the European Union's precautionary approach refers back to the problems on uncertainty discussed by Funtowicz and Ravetz (1990; 1993) in that these uncertainties arise from hazards that cannot be assessed accurately in the current risk assessment framework. It is the presence of scientific uncertainty and not a scientific risk assessment that is crucial to the debate over proper GMO regulation.

One key element in the use of the precautionary principle for GMO regulation is unrestricted information. While the risk assessment paradigm "accepts confidentiality of information to protect corporate proprietary rights, the application of the precautionary principle

requires full disclosure and accessibility of information" thereby rendering it a more open, democratic process of protection against the risks of technology (Quijano 2003: p. 25). As described by the European Commission, the precautionary approach to GMO regulation is a three stage process involving a trigger stage, a decision stage and a selection stage (Carr 2002). For the precautionary principle to be considered, potential harm to the environment or human health must be identified; "if the scientific evidence is insufficient, inconclusive, or uncertain and there are reasonable grounds for concern, then the precautionary principle may be invoked (Carr 2002: pp. 33-34). While the trigger stage for considering the precautionary principle is grounded in science, the decision to actually adopt the precautionary principle is purely political. Policymakers must balance the concerns of industry with the well-being of citizens and the environment. If policymakers decide to adopt the principle, then the next stage involves the selection of appropriate measures, such as a measure that is legally binding or simply a decision to inform the public of possible hazardous impacts from/of the specific product. As Susan Carr (2002) argues, it is in the political stage, the decision on whether or not to adopt the principle, that many of the subjective and value-based aspects are introduced. The Western European tradition of social welfarism (Kleinman and Kinchy 2003) encompasses a wider range of social values on which policy can be based. It is also important to note that in the European perspective, it is the process of genetic modification of food that needs to be regulated and not simply the product of biotechnology as reflected in U.S. regulatory policy (Jasanoff 2005). This regulatory regime also reflects a different view of agriculture, one that is not solely focused on industrial production. Europeans do not view agriculture as only an industry; in Europe, agriculture "fulfills a multifunctional role, including supporting the rural way of life, preserving

the culture and heritage of the countryside, ensuring the welfare of animals, and protecting the environment" (Isaac 2002: p. 205). European consumers have also faced several food crises, including the BSE crisis in the UK (Aldhous 2000), a critical event that signaled a loss of trust in the capacity of government to protect its citizens.

With its policy developments during the 1980s, the European Union regulatory regime actually incorporated aspects of both the scientific rationality and social rationality paradigms of Isaac's (2002) risk framework. This not only reflects different views within the EU's member states but also reflects different views within the 40 Directorates-General (DGs) that make up the European Commission, the regulatory institution of the European Union (European Commission 2009). The major DGs that influence the regulatory policy concerning GMOs are Industry (DG III), Agriculture (DG VI), Science, Research and Technology (DG XII), Environment (DG XI) and, at times, Consumer (DG XXIV), but usually only in a supportive capacity. This fragmented approach to policymaking allows for a much wider participation in the creation of environmental regulation. The Viehoff Report, published in 1986, presented the first European Community-wide set of directives intended to create harmonization in the regulatory process of GM products and prevent unilateral action among the member states. The different ideological and philosophical viewpoints emerged at this time as the decision-making process in the European Community implemented both a horizontal and vertical approach to regulation. The different Directorates-General exhibited elements of both commercial and industrial objectives as well as the social dimensions of biotechnology. The Industry, Agriculture and Science Directorates-General all supported the scientific-rationality paradigm, placing an emphasis on economic interests. However, this does not mean that they did not stake an interest in protecting the

environment or ensuring the safety of human health, rather "they simply perceived that the potential risks or hazards were from products, not from technology and that the regulatory focus should be on the…product" (Isaac 2002: p. 212) thus echoing the same regulatory philosophy of the United States. The Environment and Consumer Directorates-General, on the other hand, favored the social rationality approach to regulation, arguing that the precautionary principle should be employed in order to protect the interests of consumers and the environment.

## Directive 90/220[2] and a Shift from Facilitating the Market to Protecting the Environment

While previous legislative directives (up to and including Directive 90/219) had been focused on health and the environment from the contained use of GM products, the Directive 90/220, passed in April 1990 on the deliberate release into the environment of genetically modified organisms, was intended to provide a more comprehensive regulatory regime. Deliberate release in this case refers to:

> "Any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms without provision for containment such as physical barriers or a combination of physical barriers together with chemical or biological barriers used to limit their contact with the general population and environment" (Ryland 2001: p. 5)

What is interesting about the development of this Directive is that only the Environment Directorate-General (DG XI) was responsible for developing the language of this legislation; unlike previous pieces of legislation, Industry (DG III) was not involved in the development of

[2] See Appendix for the full text of Directive 90/220

this new Directive. The legislation on the deliberate release of GMOs into the environment was intended to provide a "process-based, regulatory oversight, ensuring uniform internal-market conditions while promoting human and environmental health in all member states" (Isaac 2002: p. 215). Approval for the deliberate release of GMOs into the environment would now require the involvement of the designated authorities in the EU member states. If the member states were not able to reach an agreement about approval, then the decision would be deferred to the European Commission. Once a product is approved for use and is placed on the market, then it may be used without further notification throughout the European Union, and no restrictions can be made by member states. Nevertheless, if a member state has "justifiable reasons to consider that the product constitutes a risk to human health," then that state, upon informing the Commission, may provisionally restrict the use of that product on its territory (Ryland 2001: p. 5).

With the introduction of Directive 90/220, the products of GMOs now faced a more stringent vertical and horizontal regulation before they could be released to the market. One similarity that this new legislation had with previous Directives, however, is that once a GM product is approved, it cannot be restricted by individual members. This Council Directive was met with a large amount of criticism from the scientific community as well as industry. The scientific community argued that scientific rationality should prevail over social rationality and that this directive would provide an unneeded burden to the scientific research process. What is interesting about these criticisms is that, in response to this negative reaction from industry, science, and its trade partners, The European Commission made amendments to the Directive 90/220 that were more focused on competitiveness and the internal market. These amendments

were then challenged by critics of biotechnology who argued that this new legislative language placed too little emphasis on the social dimensions and did not include provisions for public dissemination of information or inclusion in the decision-making process.

The first amendment to Directive 90/220 was Commission Directive 94/15/EC which was enacted in April 1994 (European Commission 1994). This amendment was created with the intention of increasing the focus of the initial Directive on European competitiveness in the biotechnology market and on enhancing the internal market structure of the European member states. Although these laws initially had a focus on precaution and restraint, the evolution of the European Council Directives shows a clear influence by industrial powers even though the Environment Directorate-General was gaining an increasing amount of legislative power in the Commission during this time. The initial position of the 90/220 Directive did not address the issue of labeling for GM products but was soon forced to address the issue once the first GM varieties of soybeans arrived from North America in 1996. Prior to this event, mandatory labeling was "only necessary when the final product [had] been substantially modified" (Isaac 2002: p. 220). Reaction by consumer groups and NGOs to this simple labeling initiative prompted the creation of the Novel Foods Regulation in 1997. The intent of this regulatory initiative was to broaden the current regulatory oversight to include products derived from GM material and not just products containing GM materials. This product-based regulation was supplemental to the 90/220 Directive which still remained in control of safety assessment. This supplemental regulation was concerned with foods whose nutritional value had been significantly changed in the production process. These products were required to be labeled, in which the label must include how the product had been changed, any ingredients that may affect

health and the presence of a GMO in order to assuage consumer concerns (Isaac 2002; Ryland 2001). The Novel Foods Regulation together with Directive 90/220 and Directive 90/219 are the three principal forms of legislation that deal with GM crops in the European Union; however each member state has a supplemental regulatory process that has some room to maneuver within the European Commission's regulatory legislation. The evolution of these three regulatory laws not only provides insight into the decentralized structure of decision-making in the European Union, but also illustrates the more open, democratic process of regulatory oversight in this region that attempts to be attentive to consumer concerns and public opinion. Reception to biotechnology in the European Union tends to be more skeptical of and even at times ambivalent toward scientific authority and scientific methods for risk assessment. Part of this may be due to distrust in government institutions to protect its citizens, but could also represent a different system of values that differentiates the European reaction to GMOs with the lack of reaction to GMOs in the United States.

## Public Opinion and Attitudes toward Food Technology

Many Europeans express uneasiness about biotechnology processes and products. While there is evidence of differences in opinion concerning GM food across member countries in the European Union, public perception of genetically modified food in Europe tends to be negative (Gaskell et al. 1999). Genetically modified food is often associated with unintended consequences and long term risks for human health and the environment. There is also the presence of moral and ethical concerns which tend to influence perception toward GMOs (Miles

et al. 2005). In many cases, the public recognizes that there may be potential benefits associated with biotechnology and GM food. The perception of these products, however, often rests on who receives these benefits and whether specific benefits of these products are actually desired. When genetically modified soya was introduced into the European food supply in 1996, there were no traceability mechanisms or labeling processes in place, meaning that consumers were "unable to choose whether or not to consume genetically-modified foods" (Miles et al. 2005: p. 247). There often seems to be a disconnect in thinking between the traditional concerns of regulators (risk and safety) and the concerns of the public in the EU which tend to focus on moral acceptability.

Conventional wisdom would lead one to believe that knowledge is correlated with support for science and technology. The more the public are informed about a particular process or innovation, the more likely they are to be supportive of the products stemming from advances in science and technology. However, an examination of several Eurobarometer studies in the 1990s (Nature 1997) implies that although the public's knowledge of relevant basic science increased, optimism about the contribution of biotechnology and the beneficial nature of advances made by genetic engineering actually declined. More knowledge does not always lead to greater public acceptance.

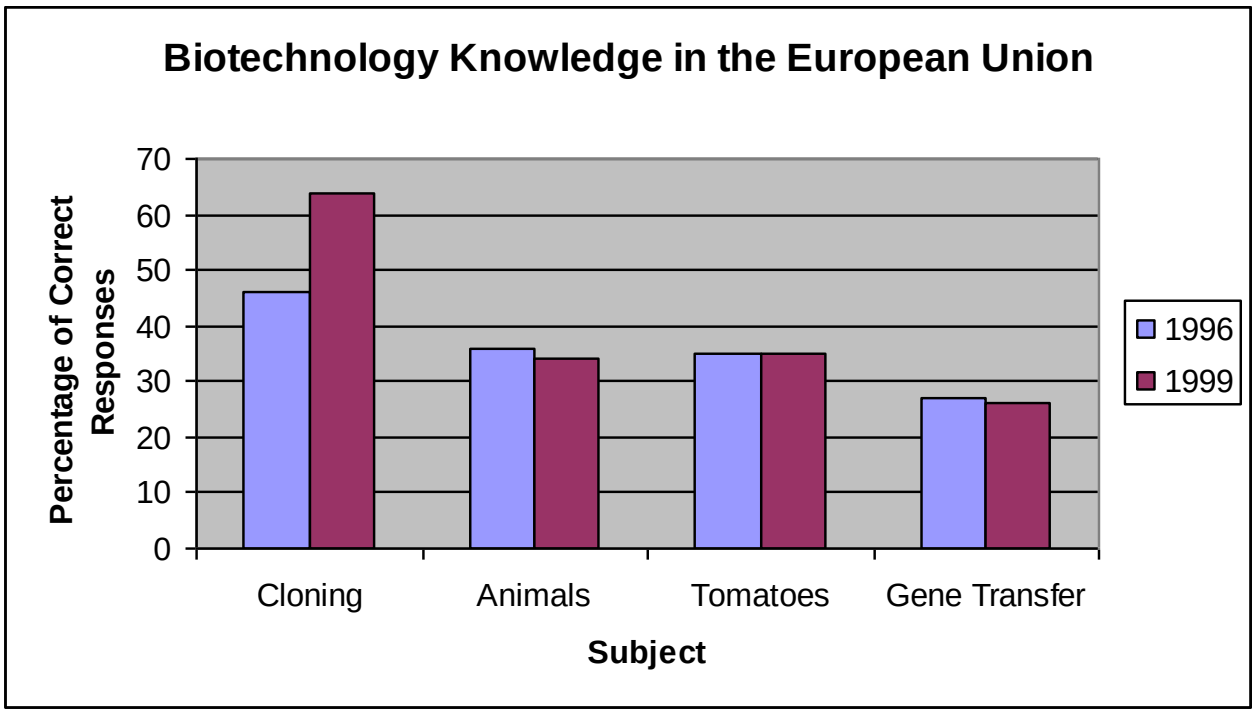


**Figure 1: Biotechnology Knowledge in the EU**
*Source: Eurobarometer 52.1 The Europeans and Biotechnology March 2000*

As illustrated in Figure 1, Europeans' knowledge of the subject of human cloning rose significantly during the three year period 1996-1999. The Eurobarometer survey asked a series of true/false questions on different genetics and biotechnology subjects where each respondent could answer "true," "false," or "don't know." While the percentage of respondents who could accurately recognize that "the cloning of human beings results in perfectly identical descendants" (Eurobarometer 52.1) rose from 46 percent to 64 percent, the knowledge questions that were asked concerning the potential of biotechnology reflect a continued uncertainty in public attitudes toward this technology. The "animals" subject was addressed by asking respondents whether or not genetically modified animals are always larger than ordinary animals. The number of correct responses for this category actually dropped over the three year period from

36 percent to 34 percent. The number of respondents who were unsure of the answer (those responding "don't know") rose during this period from 30 percent to 38 percent. For the "tomatoes" subject, respondents were asked to determine the validity of the statement: "ordinary tomatoes do not contain genes, while genetically modified tomatoes do" (Eurobarometer 52.1). The percentage of respondents who were able to correctly answer this question remained unchanged from 1996 to 1999 at 35 percent. The percentage of respondents who answered incorrectly, however, increased from 30 percent to 35 percent during this period. This could imply that Europeans are unsure or confused about the technology concerning genetic modification of food. While on the one hand, European respondents' knowledge and comfort with the subject of human cloning significantly increased from the 1996 to the 1999 survey, the genetics of food and crop modification still elicit a sense of uncertainty among the public. The last subject category addressed was gene transfers, specifically whether or not it is impossible to transfer animal genes to plants. The majority of respondents in 1999 (47%) were unsure about this subject and were unable to ascertain the validity of this statement. The percentage of respondents who correctly answered this question on the biotechnology quiz dropped slightly from 27 percent in 1996 to 26 percent in 1999, though not at a significant rate. A more telling development here is that the percentage of respondents who did not know whether or not this was possible increased during this time period, meaning that the uncertainty surrounding genetic modification and gene transfers has influenced the regulatory policy in the EU which emphasizes the consumer's right to know about GM products. This concern, however, does not extend to the potential consequences for the natural world of modifying the basis of life in plants or animals; it merely touches upon the risk to human health and the usefulness of this technology to improve

human life, not improve biodiversity or the natural world. While European attitudes may address specific moral concerns about biotechnology and its products, these concerns remain nested in an anthropocentric framework which does not seem to consider nature as an actor in determining whether or not this type of technology is truly beneficial.

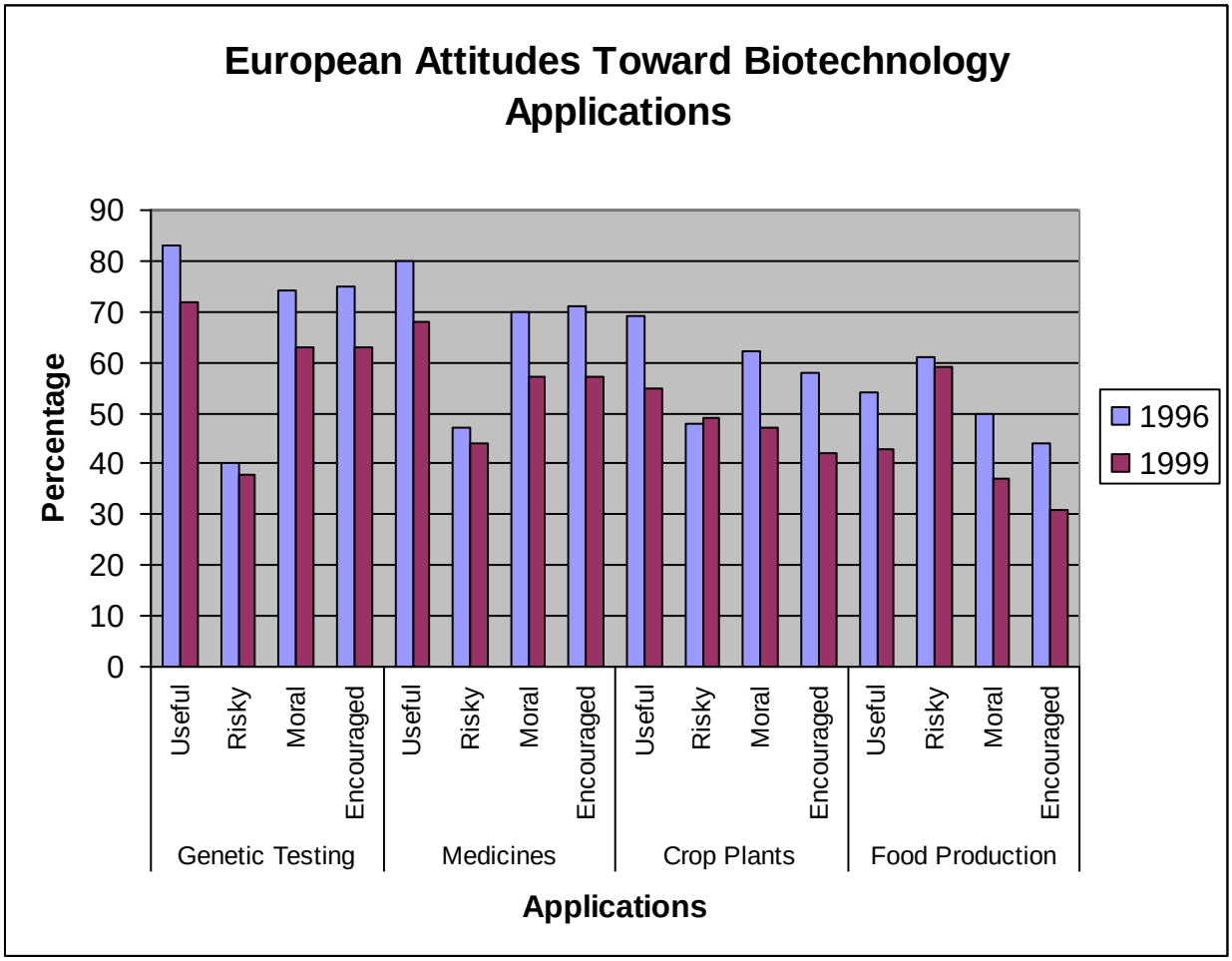


**Figure 2: European Attitudes Toward Biotechnology**
*Source: Eurobarometer 52.1 The Europeans and Biotechnology March 2000*

The 1999 Eurobarometer survey included a basic biotechnology quiz to determine the level of knowledge that respondents had regarding genetics and biotechnology. Along with this index of biotechnology knowledge, respondents were also surveyed on their perception of

biotechnology and genetic modification in specific industrial applications. Figure 2 illustrates the changing perception of biotechnology from the mid-1990s to the end of the decade. While respondents' knowledge of basic genetic practices increased as illustrated by the human cloning question from Figure 1 above, their perception of biotechnology applications follows a consistent pattern. As clearly shown by this data, in 1999, respondents viewed the use of biotechnology in genetic testing and medicinal applications as less risky than they viewed it in 1996. Nevertheless, in the applications of crop plants and food production, the respondents viewed the use of biotechnology as riskier in these areas in 1999 than they did in 1996. This also coincides with research undertaken by Gaskell et al. (2001) which showed trans-Atlantic support for biotechnology in the use of genetic testing and medicines, but a clear divergence between the United States and the European Union in crops and food production. Europeans do not clearly oppose all forms of genetic manipulation; the trans-Atlantic divide "appears to be limited to the 'green biotechnologies'" (Gaskell et al. 2001, p. 108). The "green biotechnologies" in this case consist of GM foods and crops. The authors here make a clear distinction between this type of biotechnology application and the "red" biotechnologies which consist of genetic testing and medicine. The key point here is to understand that the negative European public perception of biotechnology focuses on GM food and crops and not on the entire process of genetic manipulation; the concern for public health and safety is illustrative of the precautionary approach initially implemented by European regulators and appears to mainly center on the uncertainty of GM food production and the process it entails.

It has been claimed (Bauer 1995) that the mismatches between the scientific and public assessments of risk are responsible for public resistance to new technologies. Respondents in the

1996 Eurobarometer survey who had concerns about gene technology were found to think "principally in terms of moral acceptability rather than risk – a significant difference from the way in which experts normally judge the acceptability of new technologies" (Gaskell et al. 1999, p. 385). Supporters of gene technology view this technology as useful, morally acceptable and something that should be encouraged whereas opponents of gene technology view this technology as risky and morally unacceptable.

**Table 1: Common Logic for Responses to Gene Technology in the EU**

| Patterns of Response | **Supporters** | **Risk-Tolerant Supporters** | **Opponents** |
|---|---|---|---|
| **Useful** | Yes | Yes | No |
| **Risky** | No | Yes | Yes |
| **Morally Acceptable** | Yes | Yes | No |
| **Encouraged** | Yes | Yes | No |

*Source: Gaskell et al. (1999)*

It is possible that the difference between scientific perceptions of risk and public perception of risk in biotechnology rests on the notion of benefits. Who benefits from biotechnological applications? In the fields of genetic testing and medicine development, there is a clear benefit to be had for society. However, the genetic modification of crops and the manipulation of genes in food production pose higher risks than benefits. Whether it is due to an increasing amount of uncertainty surrounding the food production process (stemming from the 1996 BSE crisis in the UK) or the desire to know what scientists have altered in a product placed on the market for consumption, gene technology applied to food and plants is not seen as a benefit to society by the European public. The regulatory progression toward acceptance of these products, with the

addition of labels that identify it as a GM food, has largely been determined by a push toward convergence on GMO regulation in the international community. The focus in the United States on the substantial equivalence of GM products to conventionally produced products has influenced the international community to converge on slowly accepting the unnatural manipulation of genes for an increase in crop yields and a more efficient food production process.

# CHAPTER FOUR: U.S. REGULATION OF GENETICALLY MODIFIED ORGANISMS

The key document that guides the regulation of genetically modified organisms in the United States is the Coordinated Framework for Regulation of Biotechnology (1986) which describes the Federal system for evaluating the products of biotechnology. This framework is a coordinated, "risk-based system to ensure new biotechnology are safe for the environment and human health" (United States Regulatory Agencies Unified Biotechnology 2009). The U.S. government agencies that are responsible for the regulation of genetically modified products are the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA) and the Department of Health and Human Service's Food and Drug Administration (FDA). Depending on the characteristics of the specific product, one or more of these agencies may provide oversight on the product's development. One key attribute to note is that in the United States, as opposed to the regulatory structure of the EU, the regulation of biotechnology is focused on the end product, not the process of manipulating the DNA structure of animals and plants. The Coordinated Framework is insistent that "organisms produced through genetic engineering are no different form organisms produced from traditional breeding techniques (Toke 2007: p. 408). Even though the process of creating genetically modified foods is different from traditional agricultural practices, the end products are viewed as one and the same. The FDA's 1992 GM Food guidelines state that GM foods are no different from their conventional equivalents, and because of this they do not present a safety concern (FDA 1992).

## The Division of Responsibilities in U.S. Regulation

In the U.S. regulatory structure, the USDA is responsible for environment assessments of plant risk and for regulating the import and interstate movement of GM plants. APHIS examines organisms and products that are altered or produced through the genetic engineering process that are or have the potential to be harmful to plants (Isaac 2002). Under the Plant Protection Act, the USDA-APHIS has regulatory oversight over biotechnology products that could pose a pest risk to plants. In this regard, the regulatory structure does concern itself with the process of genetic engineering but only in an elementary capacity. In fact, the regulatory procedures of APHIS have been simplified twice, once to de-list six GM varieties and once to speed up the application review for a non-regulated status to GM plants. Concerning the regulation of GM food products, the Food and Safety Inspection Service (FSIS), housed within the USDA, is responsible for ensuring the safety and proper labeling of products that are prepared from domestic livestock. Any food animals that are subject to the techniques of biotechnology would fall under the jurisdiction of the FSIS. According to the language of the Coordinated Framework, the FSIS "anticipates that many food animals which are subject to the new techniques of biotechnology will not differ substantially in appearance, behavior, or general health from currently inspected cattle, sheep, swine, goats, equines and poultry" (Office of Science and Technology Policy 1986, p. 110). This statement allows the FSIS to incorporate the same inspection and regulation procedures that they would for any traditional food animal inspections. The framework allows for the fact that certain genetically engineered animals may differ substantially from animals currently inspected; however, a decision on how to proceed in the inspection and regulation process would not be made until the time at which these animals become part of the food

production process. Instead of making amendments now to the regulatory structure, the policy according to this framework is one of adaptation as needed, which fits in with the scientific rationality paradigm of regulatory politics. The scientific rationality approach relies on the rationality of empirical questions and adheres to a faith in technological progress, not precaution. Actual risk is separated from perceived risk in GM crop regulation. For the United States, the key determinant in altering the regulation of GM crops and food products is whether a risk exists and the likelihood that this risk will occur. As noted above in the regulatory language for the FSIS inspection process, until genetically engineered animals differ significantly from their traditional counterparts in appearance, behavior or general health, the risk is perceived as equivalent to that of traditional food animals in the industrial food production process.

The EPA is responsible for the environmental release of bioengineered pesticides and bioengineered plants with pesticide characteristics, such as Bt corn and Bt cotton. A process-based focus is initially employed to determine crops that fall within the EPA's jurisdiction; however, a "scientific-rationality approach is used in the risk-assessment stage…in order to determine novelty" (Isaac 2002: p. 185; Jasanoff 1995). The switch from a process-based approach to risk management to a more product-based approach is indicative of the desire by industrial powers to give the appearance that the process involved in gene modification is no different than ordinary measures of crop and food production, especially since farmers have been creating hybrid plants for years. The difference, however, lies in the industrial modification through the use of technological processes to fundamentally alter the genetic structure of these plants and food products. Inserting foreign genes into a plant should be considered different from creating a new species of plant from two naturally occurring plant species. During the

comment period before the Coordinated Framework was implemented, many of those submitting comments expressed concern that the EPA was relating an organisms' risk potential to the process by which it was created and not on the product itself. Those offering comments suggested that "the process by which an organism was modified was too indirect as an indicator of its newness" (Office of Science and Technology Policy 1986, p. 39). The comments received by the EPA indicated that there should not be a differentiation between the process of genetic engineering and other industrial processes. The process-based approach that the EPA initially wanted to implement in its oversight of biotechnology products was believed to be "an insufficient indicator of risk, because genetic engineering processes do not necessarily produce organisms that present risks, nor are non-engineered organisms necessarily safe" (Office of Science and Technology Policy 1986, p. 39). One important series of comments that were submitted to the EPA during this time referenced the possibility of market distortion. A process-based approach would single out specific production techniques for regulation thus causing the more traditional techniques to be favored at the expense of newer, scientifically advanced techniques that could be just as safe as or even safer than the traditional production techniques. The possibility of market distortion is important to highlight here in order to emphasize the economic perspective that encompasses the U.S. regulatory structure for GM products. This economic perspective serves to reiterate the scientific rationality paradigm that best describes the set of values and attitudes toward the genetic modification of nature for industrial profit. The EPA of course does take responsibility for examining the environmental impact of these processes but the agency is limited in the scope of its regulatory oversight to different

applications in the industrial agriculture process, such as pesticides and herbicides, and is not responsible for regulating the production of specific plants or food products.

The FDA has the responsibility over ensuring food safety and the safety of crops that are used for feed in the industrial agriculture system. As described in the Coordinated Framework:

> "A small but important expanding fraction of the products the Food and Drug Administration (FDA) regulates represents the fruits of new technological achievements. These achievements are in areas as diverse as polymer chemistry, molecular biology, and micro-miniaturization. Although there are no statutory provisions or regulations that address biotechnology specifically, the laws and regulations under which the agency approves products place the burden of proof…on the manufacturer. The agency possesses extensive experience with these regulatory mechanisms and applies them to the products of biotechnological processes." (Office of Science and Technology Policy 1986, p. 24)

By examining this language, it is clear that the same regulatory procedures placed on ordinary, normal products by the FDA are also being used to regulate the products of biotechnology. The language incorporated into the Coordinated Framework emphasizes the achievements of technology and places the area of examination on the product and not the process by which it was created. Nowhere in this language do the issues of the ethics of genetic manipulation or the potential consequences of altering the evolutionary structure of life appear.

One thing that is important to note is that FDA consultation is not mandatory but is only recommended prior to the market release of GM food and feeds. This is due to the fact that the FDA does not differentiate between the end products of GM food and food that is produced using traditional methods of agriculture. According to the FDA, the focus of oversight should be on the novelty of food plants, not on the use of biotechnology (FDA 1992). Biotechnology-based products are to only be brought under FDA jurisdiction if they are determined to be a food additive according to the Federal Foods, Drugs and Cosmetics Act (FFDCA).

**Table 2: Summary of U.S. Regulatory Agency Approval Structure**

Summary: Approval of Commercial Biotechnology Products

| **Subject** | **Responsible Agency(ies)** |
|---|---|
| Foods/Food Additives | FDA |
| | FSIS (division of Dept. of Agriculture) |
| Human Drugs, Medical Devices, and Biologics | FDA |
| Animal Drugs | FDA |
| Animal Biologics | APHIS (Animal and Plant Health Inspection Service) |
| Other Contained Uses | EPA |
| Plants and Animals | APHIS |
| | FSIS |
| | FDA |
| Pesticides Released into the Environment | EPA |

*Source: U.S. Office of Science and Technology*

## Scientific Rationality and the Economic Perspective

The scientific rationality framework provides stability and a sense of predictability for the U.S. biotechnology industry. With its emphasis on technological progress and efficiency, it makes sense that the regulatory submission process is straightforward and consists of a minimum number of barriers for acceptance of a product. An example of this efficiency and predictability is illustrated by Monsanto's compliance efforts in the mid-1990s in seeking approval for its GM potato. This particular Russet potato variety, called the NewLeaf potato, was developed to be resistant to the Colorado potato beetle. The NewLeaf potato uses naturally occurring bacteria called *Bacillus thuringiensis* to provide protection against the Colorado potato beetle in the plant

(Monsanto 2009). As an example of U.S. efficiency in the GM product approval process, the Monsanto case illustrates the trend of high rates of approval with few regulatory blockages. The Monsanto strategy in the case of its GM potato consisted of two phases. The first phase of their strategy was to establish the fact that the GM potato was equivalent to traditional varieties of potatoes and therefore should not be subject to novelty regulations (Isaac 2002). The second strategy that Monsanto employed was to provide the correct data that was needed on the human, animal, and environmental safety of the product. The certainty and predictability of the GM regulatory process in the United States allows biotechnology companies to know what types of hurdles they will encounter and the type of risk assessment information that they should present in order to gain approval for market release. These firms favor the regulatory approach of the United States and have been able to push for this type of approach in the international community via the World Trade Organization and its dispute resolution process. The scientific rationality approach benefits economic interests through its predictable framework and narrow conception of risk that encourages technological progress at the expense of potential environmental harm, a consequence that, under this paradigm, would only require action or adaptation upon its occurrence.

GM crop regulatory submissions in the United States require three types of information to proceed through the acceptance process for market approval. The biotechnology firm that has developed the GM product in question must submit information on the genetic characteristics of the host and recipient organisms, "the vector of transfer employed" in the creation of the product, and information on the genetic characteristics of the final product created by the transfer (Isaac 2002, p. 192). The second type of information that is required is information on the method of

data collection and procedures used for the field trials. The third type of information that must be submitted for market approval of the GM product is the location of the field trial and the supervision procedures that were employed in the field trials. Once a biotechnology firm has gone through this process successfully and has received approval for a GM crop variety, "the only regulatory responsibility is an annual field-trial report" (Isaac 2002, p. 192). The U.S. regulatory approach for GM products is indeed a commercially friendly approach. Between 1988 and 1998, the Animal and Plant Health Inspection Service (APHIS) received more than 920 requests for the environmental release of GM crop varieties. Of these 920 requests, 886 were approved. Also during this time period, APHIS received 65 petitions for deregulation of certain GM varieties; only 5 were rejected.

The product-focused scientific rationality approach employed in the United States is one that is based on the application of biotechnology processes and one that employs a principle of substantial-equivalence, as illustrated in the language of the Coordinated Framework (1986), instead of viewing all GM crops as novel products. This product-based approach is much more likely to be favored by biotechnology firms and industrial actors whose sole responsibility is to ensure that their GM product is equivalent to a product created through traditional means. The fact that the DNA structure in many cases has been altered would seem to render this equivalence invalid. Nevertheless, the process by which the new GM product was created and the possible ecological impacts incurred are never called into question by the regulatory agencies. This type of regulatory framework favors economic responsibility over that of social responsibility. The fact that a product that has had its genetic structure fundamentally altered can

be considered "equivalent" to one that has grown in a conventional method attests to this focus on the market and economic progress.

## Similarities or Differences in Regulatory Approaches?

The regulatory process concerning biotechnology in the United States differs from the European Union in that it employs a very narrow range of participation in the process. Experts perform the risk assessments, either federal regulators or the risk-assessment personnel of the proponent GM-crop developer like Monsanto, and the decision making power rests with a small group of scientists, government bureaucrats and members of industry. As described in the example of the Monsanto GM potato, many biotechnology firms are responsible for performing the risk assessment and then forwarding that information to the applicable U.S. regulatory agency. Most often, these risk assessments are adequate for the approval process, a process that tends to favor industrial firms and technological progress. It can be argued that these actors all have a vested interest for the most part in the growth of the genetic engineering industry. However, despite the narrow participation in the decision-making process, there does exist the opportunity for public comment on draft policies. This would require though that citizens are concerned enough with the genetic engineering process to submit comments on these draft proposals and monitor the Federal Register for these announcements as well.

When the policies of the Coordinated Framework were first drafted by the relevant U.S. agencies, public comments were solicited. In the case of the USDA's regulatory policy toward GM crops and food, the agency received comments from 102 respondents, the majority of which were from either business or academia. The comments on the nature of modern biotechnology

products are telling in that they illustrate the apparent lack of concern that most respondents had toward the alteration of life's building blocks to produce a more efficient product. Only three respondents felt that "genetic engineering across species barriers did create a potentially different product and the possibility of unique ecological effects" (Office of Science and Technology Policy 1986, p. 113). Only seven respondents (6 percent) commented on the topic of risk assessment and risk analysis. Comments on risk assessment and a risk/benefit analysis of biotechnology applications ranged from a recommendation that standard methodologies be applied by all agencies for risk assessment to warnings against attempting the regulate the imaginary dangers of genetic engineering and recombinant DNA techniques. Comments received by the FDA and the EPA regarding policies toward GM crop and food production followed a similar pattern, with the majority of comments emanating from the business and academic world. It would appear from these comments that there is a greater trust in science and technology in the United States, or at least a greater amount of trust in government to apply the correct amount of regulation to the products of genetic engineering.

One additional dimension to U.S. regulatory development of GMOs rests with the Office of Management and Budget (OMB) which assesses proposed U.S. regulations and legislation to ensure that new regulations will generate desired outcomes. These evaluations support the scientific rationality approach in that the OMB's approach limits stakeholder engagement in the risk-management process because "such involvement can potentially distort the regulatory development beyond the goal of correcting market failure" (Isaac 2002: p. 188). The OMB evaluations support a risk assessment process that is based on hypothetical risks only, not speculative risks that are more adapted to a precautionary approach. The OMB is only

concerned with focusing on safety and hazards and not on assuaging public fear and concerns. This type of regulatory structure differs greatly from the EU regulatory framework which adds a political dimension into the prevailing paradigm, rendering not only a responsibility to economic development, but also a responsibility to the public realm. One of the largest differences between the two regulatory frameworks is the range of participation that is allowed in the process of creating and implementing regulatory policy for GM crops and food products. While the United States employs a narrow range of participation, following the scientific rationality paradigmatic structure, the EU allows for a wider participation in regulatory approaches to genetic engineering. Causes for this difference may rest with media coverage as certain authors (Gaskell et al. 1999) have found a pattern in the type of coverage European media outlets give to the GM controversy. Nevertheless, a greater cause for this widening participation gap across the Atlantic seems to be the level of centralization and fragmentation of the regulatory process. While the United States' regulatory regime is fragmented across agencies and even between federal and state powers, the European Union's regulatory structure has become increasingly centralized over the past decade, with the majority of decision-making resting with the European Commission and the European Council. Individual countries still retain some leeway in regulating products that are imported across their borders, but the bulk of policy formulation lies within these two institutions, making it easier for citizens to know where to address their concerns.

The rhetoric that Europe promotes a greater level of precaution in its approach to regulation follows the social rationality paradigm that Isaac (2002) employs to differentiate the EU framework from that of the United States. However, this paradigm does not rely solely on

the dichotomy between progress and precaution. If this were the case, then the placement of the United States and the European Union as having fundamentally different values and approaches to environmental concerns would collapse. This rhetoric of a greater amount of precaution in the European regulatory process does not fully encapsulate the reality of actual regulatory policies. The choice of risks to regulate plays a larger role in the creation of divergence between these two actors; "Europe appears to be more precautionary than the U.S. on some risks, such as genetically modified foods, hormones in beef, climate change, marine pollution. The U.S. appears to be more precautionary than Europe on other risks, such as mad cow disease…air pollution… [and] nuclear power" (Wiener 2004, p. 90). There is precaution on both sides of the Atlantic, but the type of risks that merit the application of precaution differs. It is also important to note that even in the case of GM food production the EU's precautionary approach does not focus on the potential ecological damage that may occur with the genetic manipulation of nature. The precautionary approach in this case has more to do with the safety of human health than it does the conservation of biodiversity or the moral acceptability of altering the basic structure of life.

The most crucial difference between the EU and U.S. regulatory approaches to GMOs lies within the labeling of GM food. Since the FDA rejects the notion that GM foods are substantially different from their conventional food counterparts, the agency also rejects the notion that GM food should be subject to mandatory labeling. Toke (2007) points out that while there have been efforts by consumer and environmental groups in the United States to urge Congress to implement mandatory labeling programs, these efforts have failed to generate enough popular concern to push these mandates through the legislative branch. The domination

of GM science by corporate interests in the United States and their close involvement with government is a matter of concern for many critics of biotechnology; however, popular sentiment seems to align itself with corporate interests, much more so than in the European Union. This corporately organized GM regulatory system in the United States fits in well with Ulrich Beck's description of the risk society, although Beck's concern with genetic technology more closely aligns with contemporary European rather than U.S. concerns.

The United States has led the rest of the world in the development of a regulatory structure for the products of biotechnology. The initial approach to regulation was driven by scientists and was based on the desire of these scientists to proceed with caution in genetic-modification techniques (Isaac 2002). It is possible that early on, these scientists had a concern with the genetic manipulation of nature and its unintended consequences, something that was later erased by industrial maneuvering for profit maximization. Indeed, Ulrich Beck (1992), arguing from a sociological perspective, regards genetic engineering to be one of the leading technological threats to the risk society:

> "Gene technology puts humankind in an almost godlike position, in which it is able to create new materials and living creatures and revolutionise the biological and cultural foundations of the family. This generalization of the principle of design and constructability…exponentiates the risks and politicizes the places, conditions and means of their origin and interpretation." (p. 200)

While initially concerned with this type of moral quandary, consumers in the European Union mostly focused on the risks involved for human consumption of GM products and not on the questions and concerns that Beck puts forth in this statement. Gene technology and the "progress" created through this technology does place man in the position of creator. This type of thinking re-emphasizes the human/nature divide and falsely places man in the dominant

position over the natural world. The ability to modify the ecological structure shifts power to a select few at the expense of future generations and ecological stability. A greater amount of scientific knowledge in this case only serves to breed a greater amount of uncertainty for sustainability. This uncertainty in environmental costs of GM production is largely left out of the bulk of social concerns and moral questioning of biotechnological processes. The economic perspective and social perspective both trump an environmental perspective in this case.

Regulatory intervention in the United States tends to follow a regulatory-independence approach that is in line with an economic perspective. This approach to regulation describes government regulatory intervention as something that should only occur in reaction to market failure. In the area of modern biotechnology regulation, the U.S. system has been focused on removing market failure in order to enhance efficiency and effectiveness, a mechanistic view in the spirit of the dominant social paradigm (Dunlap and Van Liere 1984) which praises efficiency, a faith in science and technology and future abundance in society. The market is responsible for deciding the effectiveness of different regulations, an effectiveness that is based on their ability to "facilitate technological progress while delivering an acceptable level of safety" (Isaac 2002, p. 181). A lack of technological progress would be looked at as a failure by the market to reward innovation. Technological progress is elevated at the behest of consensual decision-making and a wide range of participants, the very fundamentals of democratic decision-making procedures. A good example of this faith in future abundance and technological progress is the Green Revolution in which industrial agriculture practices were exported to the developing world in an attempt to eradicate starvation and support growing populations. In this case, however, countries like India and China are now seeing the effects of Green Revolution

techniques in that certain natural resources, like soil quality, have been eroded due to high yield agriculture techniques and the planting of GM seeds, many of which require a greater amount of fertilizers and pesticides. This cycle serves to perpetuate the influence of industrial biotechnology firms under the guise of promoting social welfare and responsibility. These cases from the developing world provide a glimpse into the environmental consequences of genetic engineering and GM crop proliferation; however, concurrent with the tenets of the dominant social paradigm, many actors in the biotechnology field simply believe that adaptation to these changes is possible.

The U.S. regulatory regime favors economic interests and scientific rationality as opposed to the EU framework of consumer interests and social rationality. While these two approaches may indicate a divergence in GMO regulation, the specific policies in place actually point toward convergence in the placement of human interests over environmental interests. While it can be argued that the European Union is more environmentally conscious of the effects of GM products, the regulatory language invoked points to the same safety and health hazards that the U.S. regulatory language includes. The difference is in the range of public participation in determining which risks require more stringent regulation and which risks are acceptable in society.

**Table 3: Comparison of Scientific Rationality and Social Rationality Paradigms**

Comparison of Scientific Rationality and Social Rationality Paradigms for GMO Regulation

| | **Scientific Rationality** | | **Social Rationality** |
|---|---|---|---|
| **Regulatory Issues** | | | |
| Belief | Technological Progress | | Technological Precaution |
| | | | |
| Type of Risk | Recognized | | Recognized, Hypothetical and Speculative |
| | | | |
| Accepts Substantial Equivalence? | Yes | | No |
| | | | |
| Burden of Proof | Innocent until proven guilty; onus is on the regulatory agencies | | Guilty until proven innocent; onus is on the producers |
| | | | |
| Risk Tolerance | Minimum Risk | | Zero Risk |
| | | | |
| Focus | Product-based | | Process-based |
| | | | |
| Participation | Narrow, usually only technical experts | | Wide; social dimensions employed; public involvement |
| | | | |
| Mandatory Labelling | Safety or hazard based strategy | | Based on consumers' right to know |

*Source: Isaac (2002)*

# CHAPTER FIVE: CONCLUSIONS

The advancement of biotechnology applications and genetic engineering of plants and food products are issues that expose not only the conflicts inherent in a dualistic understanding of the human/nature relationship, but also the conflicts between economic and social responsibility, and progress versus precaution. The political approach toward genetic modification of life forms initially presents itself as following one of two paths: risk assessment practices that favor technological progress or the implementation of precautionary measures that favor a greater social responsibility for protecting the health and safety of citizens. However, a closer examination of the regulatory language and public sentiment toward biotechnology applications has illustrated that while these two competing paradigms of regulation contain subtle differences, there are also a number of similarities that exist. Both paradigms employ a certain level of precaution toward genetic engineering and the development of genetically modified food and crop varieties; however, the subtle differences lie in the categories of risk that are examined. Where the United States' regulatory regime relies on scientific, empirical data to assess either current or hypothetical risks to this process, the EU's regulatory regime also incorporates the category of speculative risk, employing greater precautionary measures under a social rationality paradigm. The convergence toward acceptance of GM products indicates that the human/nature dualism remains strong even in a regulatory system claiming to harbor concerns about the ecological impacts of genetic engineering. Nowhere in the regulatory language or the public reaction to this technology, however, is the case made that genetic engineering does fundamentally alters the natural structure of these products and may in turn provide unintended consequences damaging the ecological system. The risks of the

modernization process, which should be incorporated in a discussion of genetic modification procedures, are largely ignored. Emphasis is placed on human health and safety, disregarding the non-human actors that may be affected by this type of progress.

The development of biotechnology and genetic engineering places an anthropocentric focus on resolving environmental problems. This focus reflects the influence of the dominant social paradigm, with its emphasis on technological progress, limited government intervention, and a reliance on the market to resolve problems, on the decision-making process for the manipulation of nature to promote human progress. The consequences of modernization, although not fully realized, are not even brought into the speculative category of risks that the European regulatory regime includes in its precautionary approach to biotechnology. The placement of values on scientific discovery, reinforcing a separation between human and non-human nature, continues to promote a utilitarian, or purely instrumental approach to nature in the cases of U.S. and EU regulation of GM products. It has been argued that the controversy surrounding GM crops and food may be caused by "legitimate differences in value commitments, including safety, social and ethical issues" (Myhr 2010, p. 8). While it does appear that an examination of public sentiment in the EU leads to this conclusion, a greater question is whether or not this view would change with an increase in knowledge of the genetic modification process. Perhaps the differences involved are not centered on values, but on the level of knowledge and the types of risks that are acceptable based on knowledge of these risks.

The main challenge for biotechnology regulation and the effects of this regulation on trade in the international community rests upon the handling of scientific uncertainty that surrounds this process. The concept of progress presupposes that more knowledge leads to less

uncertainty. Nevertheless, in the area of GM crops, research may resolve this uncertainty but it may also lead to the identification of new areas of uncertainty. Funtowicz and Ravetz (1990; 1993) address this issue in their explication of post-normal science and the misleading nature of quantitative data for scientific knowledge. Recall that the authors here argue that new issues of the post-normal age differ from traditional scientific problems in that they are global in scale, have a long-term impact, and the quantitative data on their effects is largely inadequate. The skills required for managing these new challenges have largely been neglected due to the reliance on the "correctness" of scientific assertions and the belief that the language of science is always precise. Society's faith in statistical data opens a trap in which the quantity of data presented is placed above the quality of data. An extension of the peer community is required in the knowledge production process. Rather than a narrow range of participation in regulating an industry that may promote uncertain ecological changes, there should be a wider range of participants in the decision-making process in order to alleviate uncertainty in policy.

As the research, development, and commercialization of genetically modified crops and seeds increases, there exists a greater need for international convergence on the regulatory framework for these products. GM products do have potential short-term benefits to society, but also harbor long-term ecological consequences that must be addressed by international regulatory frameworks. It is interesting to note that the U.S. and EU regulatory regimes differ mainly on the differentiation between process and product, and not on a concern for humans versus concern for nature. Enclosure of the genetic commons is not once viewed as a concern for future sustainability. Because of this, the two paradigms of scientific rationality and social rationality are not necessarily in conflict with each other; a convergence of the two competing

paradigms is possible, one in which public confidence is increased and consumer choice is ensured. The labeling policies adopted by the European Union reflect this type of convergence, whereby GM products are acceptable as long as consumers retain the right to know what they are purchasing. The troubling aspect of this convergence is that it leads to further enclosure through the advancement of intellectual property rights and the slow eradication of traditional knowledge in agricultural practice. This not only holds implications for the international community as a whole, but also greatly influences the agricultural practices of the developing world and the ability of these countries and culture to retain that traditional knowledge in the face of industrial homogenization.

The recent case of GM eggplant development in India illustrates a conflict that is creeping in more and more in the agriculture systems of the developing world: conflicts arising between the protection of crop biodiversity and the Western concept of scientific progress. In February 2010, the Indian Minister of Environment and Forests, Jairam Ramesh, imposed a moratorium on genetically modified eggplant (Bt Brinjal) until it could be sufficiently determined that this modified eggplant did not pose any risks to human and animal health and biodiversity (Rao 2010). There is great concern in this case that this genetic alteration of the eggplant crop will have adverse effects on the country's rich biodiversity. This decision was immediately criticized by Western biotechnology firms and scientists who proclaimed that the Indian government had based its decision on the "activist claims" that Bt Brinjal would negatively impact ecology and biodiversity (Rao 2010). Uncertainty toward the ecological effects of industrial practice and the genetic modification of seeds not only stems from a lack of knowledge on the issue of GM crops but also the consequences of Green Revolution agricultural

techniques. Farmers in the state of Punjab abandoned traditional methods of farming in the 1960s and 1970s as part of a national program backed by U.S. and international advisors. Indian farmers then began growing crops according to the American conventional model of agriculture: high yield seeds, chemicals and irrigation. While the short-term effects were tremendous and actually allowed India to export some grain, the pressure to grow only high-yielding crops instead of a traditional mixture resulted in a severe loss of irrigation capabilities. The miracle seeds that produced higher yields also required much more water than natural rainfall provided, forcing many farmers to dig wells and irrigate with groundwater (Zwerdling 2009). Recent government studies in India have indicated that this use of groundwater to irrigate crops has dropped the water table dramatically. The abandonment of traditional methods to increase efficiency and maximize total production has now resulted in the unintended consequence of resource destruction and an exacerbation of economic inequality. This is one consequence that the Indian government does not wish to encounter again with the production of seeds that have been genetically modified. It is not only a question of uncertainty, but also of the homogenization of crop varieties and the potential consequences for the ecological system. While providing short term gains, GM products that increase yield or provide resistance to destructive bacteria may actually produce ecological destruction in the long term, a development that industrialized nations must take notice of in the creation and implementation of regulatory policy for genetic engineering practices. The Indian government has recently begun taking a cautious approach to GM crop development, including "considering a proposal that GM crops, in addition to passing several field trial criteria, will have to be proven to be nutritionally superior

to their ‘natural’ counterpart before they can be commercialized” (Knight and Paradkar 2008, p. 1031).

The concerns from the developing world regarding GM crop and food production focus not only on the process of genetic manipulation but also on the final product resulting from this manipulation. Where the U.S. regulatory regime is only concerned with the final product and sees no difference between a GM product and a traditional product, it is both the process and the product that must be examined to alleviate the uncertainty involved in this scientific process. While there is always the presence of uncertainty and anomaly in scientific discovery, it is with the processes of biotechnology that greater knowledge leads to greater uncertainty. Therefore, a middle ground for regulating this process is needed, one in which the concerns of industrial firms and the concerns of the public are both acknowledged. The economic perspective must be joined with a greater social responsiveness to the citizens who consume these products. To maximize long-term benefits and mitigate ecological damage, it is imperative that governments incorporate non-human actors into the policy debate, taking notice of potential environmental damage and biodiversity loss that may be incurred from human manipulation of the natural world.

# APPENDIX: COUNCIL DIRECTIVE 90/220/EEC

# Council Directive

# of 3 April 1990

# on the deliberate release into the environment of genetically modified organisms

# (90/220/EEC)

## THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;

Whereas living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States; whereas the effects of such releases on the environment may be irreversible;

Whereas the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment;

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market should, inasmuch as they concern health safety, environmental and consumer protection, be based on a high level of protection throughout the Community;

Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;

Whereas it is necessary to establish harmonized procedures and criteria foe the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;

Whereas a case-by-case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

Whereas the introduction of GMOs into the environment should be carried out according to the 'step by step' principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;

Whereas no product containing, or consisting of, GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use;

Whereas it is necessary to establish a Community authorization procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;

Whereas any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of a product containing, or consisting of, GMOs, where the intended use of that product involves its deliberate release into the environment, shall submit a notification to the national competent authority;

Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;

Whereas after notification, no deliberate release of GMOs should be carried our unless the consent of the competent authority has been obtained; Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;

Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;

Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;

Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;

Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

---

(1) OJ No C 198, 28. 7. 1988, p. 19 and
OJ No C 246, 27. 9. 1989, p. 5.
(2) OJ No C 158, 26. 6. 1989, p. 225 and
OJ No C 96, 17. 4. 1990,
(3) OJ No C 23, 30. 1. 1989, p. 45.

HAS ADOPTED THIS DIRECTIVE:

## Article 1: Scope and Objectives

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:

- when carrying out the deliberate release of genetically modified organisms into the environment,

- when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

## Article 2: Legal Definitions

For the purposes of this Directive:

(1) 'organism'is any biological entity capable of replication or of transferring genetic material;
(2) 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;
(ii) the techniqueslisted in Annex I A Part 2 are not considered to result in genetic modification;
(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as'physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;
(4) 'product'means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is paced on the market;
(5) 'placing on the market' means supplying or making available to third parties;
(6) 'notification'means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';
(7) 'use'means the deliberate release of a product which has been placed on the market. The persons carrying our this use will be referred to as 'users';
(8) 'environmental risk assessment'means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

## Article 3: Non Regulated Items

This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

## Article 4: Responsiblities of Member States

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

## Article 5: Notification Procedures

Member States shall adopt the provisions necessary to ensure that:

(1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;
(2) the notification shall include:
(a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:
(i) general information including information on personnel and training,
(ii) information relating to the GMO(s),
(iii) information relating to the conditions of release and the receiving environment,
(iv) information on the interactions between the GMO(s) and the environment,
(v) information on monitoring, control, waste treatment and emergency response plans;
(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;
(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.

The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;
(6) In the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after that authority has given its written consent, the notifier shall immediately:
(a) revise the measures specified in the notification,
(b) inform the competent authority in advance of any modification or as soon as the new information is available,
(c) take the measures necessary to protect human health and the environment.

## Article 6: Review Procedures

1. On receipt and after acknowledgment of the notification the competent authority shall:

- examine it for compliance with this Directive,
- evaluate the risks posed by the release,
- record its conclusions in writing, and if necessary,
- carry out tests or inspections as may be necessary for control purposes.

2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or
(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.

3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:

- is awaiting further information which it may have requested from the notifier,

or

- is carrying out a public inquiry or consultation in accordance with Article 7 shall not be taken into account.

4. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

5. If the competent authority considers that sufficient experience has bee obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.

6. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

## Article 7: Public Awareness

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

## Article 8: Termination Reporting Procedures

After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at later stage.

## Article 10: Compliance Requirements

1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:

- written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;

- the products comply with the relevant Community product legislation;
- the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.

2. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.

3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

## Article 11: Notification Procedures

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:

- the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessment of any risks for human health and the environment related to the GMOs or a combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;
- the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and /or carried out by the notifier either inside or outside the Community.

3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.

5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent. 6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

- revise the information and conditions specified in paragraph 1,
- inform the competent authority, and
- take the measures necessary to protect human health and the environment.

## Article 12: Review Procedures by Competent National Authorities

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or
(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2 (a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11 (1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11 (6), it shall immediately inform the Commission and the other Member States.

5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

## Article 13: Review Procedures at Community Level

1. On receipt of the dossier referred to in Article 12 (3), the Commission shall immediately forward it to the competent authorities all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection - for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

## Article 14: Labeling and Packaging

Member States shall take all necessary measures to ensure that product containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in Articles 12 and 13.

## Article 15: Free Movement of Goods

Member States may not, on grounds relating to the notification and written consent of a deliberate release under this Directive, prohibit, restrict or impede the placing in the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

## Article 16: Revocation of Free Movement of Goods

1. Where a Member State has justifiable reasons 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 these and/or 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.

2. A decision shall be taken on the matter within three montsin accordance with the procedure laid down in article 21.

## Article 17: Public Awareness

The Commission shall publish in the Official Journal of the European Communities a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

## Article 18: Reporting Procedures at Community Level

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.

2. The Commission shall send to the European Parliament and the Council, every three years, a report on the control by the Member States of the products placed on the market under this Directive.

3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

## Article 19: Confidentiality & Intellectual Property Rights

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions. 4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:

- description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;
- methods and plans for monitoring of the GMO or GMOs and for emergency response;
- the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

## Article 20: Amending Review and Notification Procedures

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

## Article 21: Member State Representation

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered

by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within tho committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

## Article 22: Information Exchange

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.

2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

## Article 23: Member State Obligations

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 October 1991.

2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

## Article 24: Publication Date

This Directive is addressed to the Member States.

Done at Luxemburg, 23 April 1990.

*For the Council*
*The Present*
*A.REYNOLDS*

# REFERENCES


Aldhous, Peter (2000). Inquiry blames missed warnings for scale of Britain's BSE crisis. *Nature, 408*, 3-5.

Atoban, A. (2004). Caught between state-sovereign rights and property rights: Regulating biodiversity. *Review of International Political Economy, 11*(4), 736-762.

Avery, D. T. (1995). *Saving the planet with pesticides and plastic : The environmental triumph of high-yield farming*. Indianapolis, Ind.: Hudson Institute.

Bailey, R. (2005). *Liberation biology : The scientific and moral case for the biotech revolution*. Amherst, N.Y.: Prometheus Books.

Barling, D. (1996). Environmental sustainability or commercial viability? the evolution of the EC regulation on genetically modified foods. *European Environment, 6*, 48-54.

Bate, R., & Morris, J. (1999). *Fearing food : Risk, health and environment*. Oxford ; Boston: Butterworth Heinemann.

Bateson, G. (1979). *Mind and nature : A necessary unity*. New York: Dutton.

Bauer, M. (1995). *Resistance to new technology : Nuclear power, information technology, biotechnology*. Cambridge ; New York: Cambridge University Press.

Bauer, M. W., Gaskell, G., Gaskell, G., Science, M., & Science, M. (2001). *Biotechnology, 1996-2000 : The years of controversy*. London: Science Museum.

Beck, U. (1999). *World risk society*. Cambridge; Malden, MA: Polity Press; Blackwell.

Bohman, J., & Rehg, W. (1997). *Deliberative democracy : Essays on reason and politics*. Cambridge, Mass.: MIT Press.

Bond, M. (2009). Risk school. *Nature, 461*, 1189-1192.

Botelho, D., & Kurtz, H. (2008). The introduction of genetically modified food in the united states and the united kingdom: A news analysis. *The Social Science Journal, 45*(1), 13-27.

Buttel, F. (2005). The environmental and post-environmental politics of genetically modified crops and foods. *Environmental Politics, 14*(3), 309-323.

Carr, S. (2002). Ethical and value-based aspects of the european commission's precautionary principle. *Journal of Agricultural and Environmental Ethics, 15*(1), 31-38.

Chambers, R. G., & Melkonyan, T. A. (2007). Pareto optimal trade in an uncertain world: GMOs and the precautionary principle. *American Journal of Agricultural Economics, 89*(2), 520-532.

Clapp, J. (2006). Unplanned exposure to genetically modified organisms: Divergent responses in the global south. *Journal of Environment & Development, 15*(1), 3-21.

Cook, G., & Pieri, Elisa, Robbins,Peter T. (2004). "The scientists think and the public feels": Expert perceptions of the discourse of GM food. *Discourse & Society, 15*(4), 433-449.

Cook, G. (2004). *Genetically modified language : The discourse of arguments for GM crops and food*. London ; New York: Routledge.

Costa-Font, J., Mossialos, E., & Rudisill, C. Are feelings of genetically modified food politically driven? *Risk Management, 10*(3), 218-234.

Cotter, J. (2003). *Troubled harvest : Agronomy and revolution in mexico, 1880-2002*. Westport, Conn.: Praeger.

European Commission (1994). *Growth, Competitiveness, and Employment: The Challenges and Ways Forward into the 21st Century*. White Paper, Luxembourg.

The European Council. (1990). *Council Directive of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms*, 90/220/EEC (Official Journal L No. 117 1990).

DeGregori, T. R. (2001). *Agriculture and modern technology: A defense*. Ames: Iowa State University Press.

Dreyer, M., & Gill, B. (2000). Germany: "elite precaution" alongside continued public opposition. *Journal of Risk Research, 3*(3), 219-226.

Dunlap, R. E., & Van Liere, K. D. (1984). Commitment to the dominant social paradigm and concern for environmental quality. *Social Science Quarterly, 65*(3), 1013-1027.

Eastman, Q. (2003). U.K. probes public opposition to GM crops. *Science, 300*, 1637-1638.

Eckersley, R. (2007). A green public sphere in the WTO?: The amicus curiae interventions in the transatlantic biotech dispute. *European Journal of International Relations, 13*(3), 329 356.

Elliott, L. M. (1998). *The global politics of the environment*. New York: New York University Press.

Europe ambivalent on biotechnology. (1997). *Nature, 387*(6636), 845-847.

Falkner, R. (2007). The global biotech food fight: Why the united states got it so wrong. *Brown*

*Journal of World Affairs, 14*(1), 99-110.

Falkner, R. (2007). *The international politics of genetically modified food : Diplomacy, trade and law*. Basingstoke England ; New York: Palgrave Macmillan.

Faure, M., & Vig, N. J. (2004). *Green giants? : Environmental policies of the united states and the european union*. Cambridge, Mass.: MIT Press.

Feyerabend, P. (1978). *Science in a free society*. London: NLB.

Feyerabend, P. (1993). *Against method*. London ; New York: Verso.

Fishman, R. M., Josephberg, K., Linn, J., Pollack, J., & Victoriano, J. (2002). European parliament approves restrictions on genetically modified foods. *Intellectual Property & Technology Law Journal, 14*(10), 22-23.

Food and Drug Administration (FDA) (1992). *Statement of Policy: Foods Derived from New Plant Varieties*, 57 FR 22984. Washington, DC: US Department of Health and Human Services.

Funtowicz, S. O., & Ravetz, J. R. (1990). *Uncertainty and quality in science for policy*. Dordrecht, the Netherlands ; Norwell, MA, U.S.A.: Kluwer Academic Publishers.

Funtowicz, S. O., & Ravetz, J. R. (1993). Science for the post-normal age. *Futures, 25*(7), 739 755.

Gaskell, G., Bauer, M. W., Durant, J., & Allum, N. C. (1999). Worlds apart? the reception of genetically modified foods in europe and the U.S. *Science, 285*, 384-387.

Gaskell, G. (2006). *Europeans and biotechnology in 2005: Patterns and trends* (Report No. 85; Eurobarometer 64.3)

Giddens, A. (1987). *Social theory and modern sociology*. Stanford, Calif.: Stanford University Press.

Giddens, A. (1990). *The consequences of modernity*. Stanford, Calif.: Stanford University Press.

Guehlstorf, N. P., & Hallstrom, L. K. (2005). The role of culture in risk regulations: A comparative case study of genetically modified corn in the united states of america and european union. *Environmental Science & Policy, 8*, 327-342.

Hacking, I. (1981). *Scientific revolutions*. Oxford Oxfordshire ; New York: Oxford University Press.

Isaac, G. (2002). *Agricultural biotechnology and transatlantic trade: Regulatory barriers to GM crops*. Wallingford, Oxon, UK ; New York: CABI Pub.

Jasanoff, S. (1990). *The fifth branch : Science advisers as policymakers*. Cambridge, Mass.: Harvard University Press.

Jasanoff, S. (2005). *Designs on nature : Science and democracy in europe and the united states*. Princeton, N.J.: Princeton University Press.

Jasanoff, S. (2006). Biotechnology and empire: The global power of seeds and science. *Osiris, 21*(1), 273-292.

Jasanoff, S., & Bauer, M. (1997). Product, process or programme: Three cultures and the regulation of biotechnology. *Resistance to new technology: Nuclear power, information technology and biotechnology* (pp. 311-331). Cambridge, UK: Cambridge University Press.

Jasanoff, S., Leach, M., Scoones, I., & Wynne, B. (2005). 'Let them eat cake': GM foods and the

democratic imagination. *Science and citizens: Globalization and the challenge of engagement* (pp. 183-198). London: Zed Books.

Kahan, D. M., Jenkins-Smith, H., & and Braman, D. *Cultural cognition of scientific consensus* (Report No. Cultural Cognition Project Working Paper No. 77)

Kempton, W., & Craig, P. P. (1993). European perspectives on global climate change. *Environment, 35*(3), 16.

Kleinman, D. L., & Kinchy, A. J. (2003). Boundaries in science policy making: Bovine growth hormone in the european union. *The Sociological Quarterly, 44*(4), 577-595.

Klintman, M. (2002). The genetically modified (GM) food labelling controversy: Ideological and epistemic crossovers. *Social Studies of Science, 32*(1), 71-91.

Kuhn, T. S. (1996). *The structure of scientific revolutions*. Chicago, IL: University of Chicago Press.

Lahsen, M. (2005). Technocracy, democracy, and U.S. climate politics: The need for demarcations. *Science, Technology, & Human Values, 30*(1), 137-169.

Lakatos, I. (1968). Criticism and the methodology of scientific research programmes. *Proceedings of the Aristotelian Society, 69*, 149-186.

Lakatos, I. (1970). History of science and its rational reconstructions. *PSA: Proceedings of the Biennial Meeting of the Philosophy of Science Association, 1970*, 91-136.

Lakatos, I., Feyerabend, P., Feyerabend, P. K., & Motterlini, M. (1999). *For and against method : Including lakatos's lectures on scientific method and the lakatos-feyerabend correspondence*. Chicago: University of Chicago Press.

Lash, S., Szerszynski, B., Wynne, B., & Wynne, B. (1996). *Risk, environment and modernity : Towards a new ecology*. London ; Thousand Oaks, Calif.: Sage Publications.

Latour, B. (1999). *Pandora's hope : Essays on the reality of science studies*. Cambridge, Mass.: Harvard University Press.

Latour, B. (2004). *Politics of nature : How to bring the sciences into democracy*. Cambridge, Mass.: Harvard University Press.

Levidow, L. (2001). The GM crops debate: Utilitarian bioethics? *Capitalism, 12*(1), 44-55.

Levidow, L. (2001). Precautionary uncertainty: Regulating GM crops in europe. *Social Studies of Science, 31*(6), 842-874.

Levidow, L., & Carr, S. (2007). GM crops on trial: Technological development as a real-world experiment. *Futures, 39*(4), 408-431.

Levy, D. L., & Newell, P. (2000). Oceans apart? *Environment, 42*(9), 8.

Losey, J. E., Rayor, L. S., & Carter, M. E. (1999). Transgenic pollen harms monarch larvae. *Nature, 399*, 214.

Lubbock, M., & Coop, A. (2002). A precautionary approach to genetic modification. *Journal of Commerical Biotechnology, 8*(3), 209-213.

Lynch, D., & Vogel, D. (2001). *The regulation of GMOs in europe and the united states: A case study of contemporary european regulatory politics*. New York: Council on Foreign Relations.

McCabe, H., & Butler, D. (1999). European union tightens GMO regulations. *Nature, 400*(6739), 7-7.

McHughen, A. (2000). *Pandora's picnic basket : The potential and hazards of genetically modified foods*. Oxford ; New York: Oxford University Press.

Merchant, C. (1980). *The death of nature : Women, ecology, and the scientific revolution*. San Francisco: Harper & Row.

Meyer, J. M. (2000). Rights to life? on nature, property and biotechnology. *Journal of Political Philosophy, 8*(2), 154.

Miles, S.; Ueland, O.; & Frewer, L. Public attitudes towards genetically-modified food. *British Food Journal, 107*(4), 246-262.

Miller, S. (2006, 9 March). EU won't set bloc-wide laws for biotech crops. *The Wall Street Journal*, pp. A. 10.

Monsanto. *The New Leaf Potato* November 2009. Accessed at: http://www.monsanto.com/monsanto_today/for_the_record/newleaf_potato.asp

Murphy, J., Levidow, L., & Carr, S. (2006). Regulatory standards for environmental risks: Understanding the US-european union conflict over genetically modified crops. *Social Studies of Science, 36*(1), 133-160.

Mushita, A., & Thompson, C. B. (2002). Patenting biodiversity? rejecting WTO/TRIPS in southern africa. *Global Environmental Politics, 2*(1), 65-82.

Mushita, A., & Thompson, C. B. (2006). *Biopiracy of biodiversity : Global exchange as enclosure*. Trenton, NJ: Africa World Press.

Myhr, A. (2010). The Challenge of Scientific Uncertainty and Disunity in Risk Assessment and Management of GM Crops. *Environmental Values, 19*, 7-31.

Newell, P. (2009). Bio-hegemony: The political economy of agricultural biotechnology in argentina. *Journal of Latin American Studies, 41*(1), 27-57.

Oreskes, N. (2004). Science and public policy: What's proof got to do with it? *Science, Policy, and Politics: Learning from Controversy Over the Skeptical Environmentalist, 7*(5), 369 383.

Oreskes, N., Conway, E. M., & Shindell, M. (2008). From chicken little to dr. pangloss: William nierenberg, global warming, and the social deconstruction of scientific knowledge. *Historical Studies in the Natural Sciences, 38*(1), 109-152.

O'Riordan, T. (2000). GM crops - civic science through partnership? *Journal of Risk Research, 3*(3), 273-275.

Paarlberg, R. (2000). The global food fight. *Foreign Affairs, 79*(3), 24-38.

Pellegrini, P. (2009). Knowledge, identity and ideology in stances on GMOs: The case of the movimento sem terra in brazil. *Science Studies, 22*(1), 44-63.

Plumwood, V. (1993). *Feminism and the mastery of nature*. London ; New York: Routledge.

Plutzer, E., Maney, A., & O'Connor, R. E. (1998). Ideology and elites' perceptions of the safety of new technologies. *American Journal of Political Science, 42*(1), 190-209.

Popper, K. R., Basic Books, p., Cooper, C. d., & Cooper, R. D. d. (1959). *The logic of scientific discovery*. New York: Basic Books.

Pretty, J. (2001). The rapid emergence of genetic modification in world agriculture: Contested risks and benefits. *Environmental Conservation, 28*(3), 248-262.

Quijano, R. F. (2003). Elements of the Precautionary Principle. *Precaution, environmental*

*science, and preventive public policy*. Washington, D.C.: Island Press, pp. 21-27.

Ramjoue, C. (2007). The transatlantic rift in genetically modified food policy. *Journal of Agricultural and Environmental Ethics, 20*, 419-436.

Rao, C. (2010). Why is India Shunning Safer Food? *The Wall Street Journal*. 3 March. Accessed at:http://online.wsj.com/article/SB10001424052748703862704575099042296849572.html?mod=googlenews_wsj.

Ryland, D. (2001). Regulating genetically modified organisms in the interests of whom? *Managerial Law, 43*(6), 1-33.

Shiva, V. (1993). *Monocultures of the mind : Perspectives on biodiversity and biotechnology*. London ; Atlantic Highlands, N.J., USA; Penang, Malaysia: Zed Books; Third World Network.

Shiva, V. (1997). *Biopiracy : The plunder of nature and knowledge*. Boston, Mass.: South End Press.

Skogstad, G., & Moore, E. (2004). Regulating genetic engineering in the united states and the european union: Policy development and policy resilience. *Policy and Society, 23*(4), 32 56.

Tait, J. (2001). More faust than frankenstein: The european debate about the precautionary principle and risk regulation for genetically modified crops. *Journal of Risk Research, 4*(2), 175-189.

Tickner, J. A. (2003). *Precaution, environmental science, and preventive public policy*. Washington, DC: Island Press.

Tickner, J.A.; Raffensperger, C. & Myers, N. (1998). *The Precautionary Principle in Action: A*

*Handbook*. Science and Environmental Health Network. Accessed at: http://www.sehn.org/precuation.html.

Toke, D. (2001). A comparative study of the politics of GM food and crops. *Political Studies, 52*, 179-186.

Toke, D. (2007). Risk, genetically modified food and the US/EU divide. *International Journal of Green Economics, 1*(3-4), 407-418.

van Dijk, T. A. (1988). *News as discourse*. Hillsdale, NJ: L. Erlbaum Associates.

Vig, Norman J. & Faure, Michael G. (eds.) (2004). *Green Giants? Environmental Policies of the United States and the European Union.* Cambridge, Mass.: MIT Press.

Weis, P. (2002). Europe prepares for arrival of GM foods. *Science, 298*, 2109-2110.

Wildavsky, A., & Dake, K. (1990). Theories of risk perception: Who fears what and why? *Daedalus, 119*(4), 41-60.

Wildavsky, A. (1987). Choosing preferences by constructing institutions: A cultural theory of preference formation. *The American Political Science Review, 81*(1), 4-21.

Wildavsky, A. B. (1995). *But is it true? : A citizen's guide to environmental health and safety issues*. Cambridge, Mass.: Harvard University Press.

Winickoff, D., Jasanoff, S., Busch, L., Grove-White, R., & Wynne, B. (2005). Adjudicating the GM food wars: Science, risk, and democracy in world trade law. *The Yale Journal of International Law, 81*(30), 1-47.

Wolfenbarger, L. L., & Phifer, P. R. (2000). The ecological risks and benefits of genetically

engineered plants. *Science*, *290*, 2088-2093.

Woolley, J. T. (2000). Using media-based data in studies of politics. *American Journal of Political Science*, *44*(1), 156.

Zwerdling, D. (2009). Green Revolution Trapping India's Farmers in Debt. *Morning Edition*. Accessed at: http://www.npr.org/templates/story/story.php?storyId=102944731.