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The role of culture in risk regulations: a comparative case study of genetically modified corn in the United States of America and European Union

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Abstract

According to the United States Department of Agriculture (USDA) and USA Environmental Protection Agency (EPA), herbicide tolerant (Roundup Ready or RR) and insect resistant (Bacillus thuringiensis or Bt) corn has ''no significant impact'' on human health and environmental integrity. In Europe, genetically modified (GM) maize strains – the identical Bt and RR biotech crops used in the USA – are banned by a ''safeguard clause'' that allows any member state of the EU to impose limited term restrictions on an approved imported or exported product. To understand these different policies, an explanatory model that analyzes political culture as a recursive phenomenon that impacts, and is influenced by, regulations must be considered. The way governments regulate modern biotechnology is not necessarily a reflection of how their political culture perceives the new scientific technology, but how their existing regulatory structure can create a political culture of acceptance or rejection for contested technological advancements. This comparative study casts doubt on interpreting agricultural biotechnology decisions solely on equations of risk analysis, and offers a detailed cultural analysis of the regulatory differentiation of modern agricultural policy between America and Europe.

Keywords: Environmental policy; Food biotechnology; Risk management; Political culture; Genetically modified

1. Introduction: genetically modified corn and the Atlantic divide

In stark contrast to the accepting regulatory regime for GM foods in the United States of America (USA), several European countries and the European Union (EU) have imposed strict limitations and precautionary approaches on the use and sale of products and processes that use the new biotechnologies. Scholars have, therefore, generated considerable attention to answering the question of why there is a differentiation in regulatory responses between the USA and the EU over the same food biotechnologies. Researchers are questioning the primacy of the objective scientific understandings of risk assessment and are attempting to single out the subjective influences or cultural preferences that must be informing policy decisions. Responses have included culture (Gaskell and Bauer, 2001), collective action (Bernauer and Meins, 2001; Buonanno et al., 2001), public outrage (Meins, 2001) and institutional structure (Vogel, 2001). While all of these factors provide insight into understanding the regulatory outcomes of the USA and the EU regarding GM foods, there is a key element often lacking in such analyses. Specifically, there is an emphasis upon single and linear patterns of causation. We argue that this results in erroneous independent findings, such as explaining the differences in GM policy by examining the USA end product-based regulation and the EU's process-based regulatory regime. To get away from this, what follows is an examination of USA and EU risk analysis of food biotechnology that tries to understand regulatory outcomes within a recursive model, where the factors identified above not only interact with each other, but are also a feedback response to the regulatory situation.

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Our recursive explanation does not advocate a competitor systems model to the traditional rational-scientific approach or alternative single culture thesis; rather it argues that regulatory regime theory must consider political culture as an embedded and reflexive phenomenon that is part of the institutional structure of a decisionmaking. Put in a more detailed way, the intent of this project is to outline how it is that cultural factors, both political and sociological, have both affected, and been affected by, the structural and anthropological parameters of USA and EU environmental policy. What we attempt to establish by following this line of inquiry is two-fold: (1) that culture can and should be used in understanding regulatory policy; (2) that treatments of culture as both subject and methodology should recognize its embedded recursive nature. What this means is that culture does not ''stand alone'' as an independent influence on regulatory decisionmaking (Echols, 1998).

In order to truly understand the rules and regulations of food biotechnology in the case of the United States and the European Union, culture must be seen as both a product and a part of the decisionmaking regime. As such, political culture cannot be treated as a variable in a risk management equation or a feedback loop in a systems model because it is a contextual phenomenon. With regard to GM regulatory risk regimes, political culture is best understood as a discourse, which has the ability to name and provide meaning to a significant policy component within environmental science or rational lawmaking. We argue that in the European case that culture did not affect the changes in the regulatory regime that considers GM maize or vice versa; rather EU history, food crises, policy debate, institutional change, and public responses interacted in a non-linear fashion to diminish the legitimacy of the EU as a regulatory and political body concerned with safety.

2. Culture, discourse, and regime theory

Explanations for the transatlantic divide over genetically modified organisms (GMO) can be organized into three areas (Gaskell and Bauer, 2001). The first lies in the differences of policy regimes and regulations. There is a greater regulatory acceptance and scientific justification for risk in North America than Europe, which fosters a greater confidence in biotechnology (Gaskell et al., 2001). The second category of explanation is the role of the media. Scholars claim that European journalists framed biotechnology with a tabloid sensationalism, which in turn encouraged opposition, but in North America the press silenced dissenters of biotechnology by not focusing on their activities (Gaskell et al., 2001). The third area focuses on the speculation that public perceptions are radically dissimilar across the Atlantic because in Europe citizens are ''technophobic'' and American citizens are ''technocrazy.'' Although cultural analyses are well represented in the comparative political science literature, such scholarship does not lend itself to the extensive scientific explanations expected by much of the discipline.

Cultural studies are topic specific because their findings are difficult to generalize. They emphasize individual analysis, use multiple forms of methodology, and establish contradictory descriptions of political culture. Thankfully, Gaskell et al. (2001) argue that culture cannot be understood as a social science variable that includes all behaviors, beliefs, and institutions. Instead they have argued that policy and regulation reflect and constitute a specific cultural context, which is very relevant to the explanation of the transatlantic biotechnology divide. Ergo, we argue that a comparative explanation of the USA and EU regulatory regimes – the complex organization of public administrators and governmental agencies concerned with agriculture and environment – will adequately identify how political institutions allow specific culture contexts to influence scientific, economic, and legal decisions about food biotechnology. Regime theory generally focuses on the attempt to understand the interactive dispute between two or more nation-states in order to solve an international problem. First formulated by Ruggie in 1975 and later refined by Krasner in 1983, regimes are described as intervening variables or ''principles, norms, rules, and decisionmaking procedures'' that affect the political and economic actors debating an issue (Pistorius and Wifk, 1999, p. 12).

The field of public policy has developed the notion of regime theory to correlate regulatory policy with political contexts – governing coalitions, the structure of relations between actors, and the resources and particular configurations of informal rules and practices – to make cross national, regional or urban comparisons (Dowding, 1996, pp. 82–84; Stone, 1989). Specifically, risk regulation regimes have been developed by political scientists to examine environmental and health-based policies from a system-based approach to organizations making public decisions about societal risks. Rather than being analyzed as single institutions that make incremental decisions about societal hazards from a scientific process, risk regulation regimes are viewed as systems of interrelated practices, parts and actors that are never rational but relatively consistent organisms of power (Hood et al., 2001, p. 9). For example, the regime for managing all of the regulatory activities that may affect genetically modified corn would consider the sociological influences on domestic farms, economic impacts to international agriculture markets, and the unintended environmental consequences of genetic breeding, such as ''super weeds,'' unknown allergic characteristics of new plant varieties, heterogeneity of food supply, changes in disease prevalence, and the loss of crop biodiversity (Holtzman, 1989).

Much of the criticism leveled toward the use of culture as a causal or explanatory concept in political science has

questioned if it is a causal, independent, intervening, or dependent variable.[1] Wishing to move away from such understandings of culture, our analysis is consistent with more recent understandings of political culture. Specifically, while there is no ''European'' culture to which one can refer, there is a benefit to be found in understanding cultures, and particularly political cultures, as neither product nor cause. As such, we propose understanding political culture, specific to Bacillus thuringiensis (Bt) corn regulation in America and Europe, as a set of political discourses that exist only in relation to other discourses, institutions, and of course, the power to establish legitimacy. Thus, instead of trying to define culture as a ''true'' referent, we can instead consider it to be a set of meanings that exist, and function, in relation to other meanings and domains in social life (Mukeji and Schudson, 1991). As such, we dismiss all general claims and dynamic explanations of culture and prefer to analyze a particular or specific context of a political culture. Our notion of a reflexive regulatory culture is practice oriented and can be used to explain the boundaries of a specific regulatory culture by pragmatically identifying the relevant features of a risk regime.

This specific, anthropological, or recursive cultural method of investigating the discourses surrounding regulatory policy provides a number of advantages over other general cultural attempts to explain the difference between GM food policy in the USA and EU. First of all, the cultural discourse theory for understanding the human and environmental health risks surrounding GM products eliminates accounts for such general claims that the French or Germans have different orientations toward food than Americans or even Canadians (Echols, 1998). For instance, journalists have claimed that Americans are accustomed to the production of ''real'' food due to the distances between farms and cities, or the prevalence of fast foods in the North American diet (Vogel, 2001). However, such claims are countered not only by the equally large portion of fast food restaurants present even in Paris, a city famed for cuisine, but also the willingness of the French to tolerate irradiated foods to a degree well above North American levels (Barber, 1996). There is, therefore, a good reason to understand culture in this context as the discourse not about food in general, but rather genetically modified foods. This discourse, however, is influenced by other phenomenon, such as historical events. For example, food crises such as BSE and even hoof-and-mouth disease can be understood as contributing to the European discourse about GM foods by providing communication on and surrounding the EU as a regulatory authority. Although these food scares are not important influences on the regulatory policies for genetically engineered corn, they aid in explaining the notion of a risk regime that analyzes risk primarily by science but also exists to manage those scientific decisions in the face of irrational concerns.

A notion of political culture defined from a reflexive perspective of risk, but informed and modified by public debates, develops an understanding of culture as a political practice that is capable of developing or facilitating its own meanings. This practice-oriented concept of culture can help explain irrational ''events or empirical regularities occur'' in the international disputes regarding modern agriculture and food biotechnology (Wedeen, 2002). Unlike most delineations of culture in political science, a practice-oriented understanding of culture allows meaning to exist inside historical contexts, permitting them to change with developing relations of power and be examined within a certain policy context (Bowen and Petersen, 1999, p. 12). This is important because ''by paying attention to the ways in which certain meanings become authoritative while others do not'', our notion of risk cultures can offer ''a view of political phenomenon by focusing on how and why'' some policy stakeholders dismiss science and law for other factors like special interest and public opinion (Wedeen, 2002, p. 714). This analysis is essential because it allows policy researchers to consider the values harbored in a political civilization as meaningful analytical concepts like economics or ideology.

We assume that the orientations Americans and Europeans hold as consumers of GM-products have been shaped by the combination and interaction of policy discourses, political arrangements, and regulatory legitimacy of the past 25–30 years. Nonetheless, we conclude that Europeans who are increasingly vocal in opposition to modified crops around the globe tend not to trust their food regulators for more important cultural reasons than because they simply experienced the outbreaks of mad cow and foot-and-mouth diseases. Similarly, we argue that there are deep anthropological and cultural explanations of why American consumers have relied on regulators and not asked too many questions about their food, which could never be explained by traditional definitions of culture or rational risk analysis. Regulatory regimes and political cultures respond to each other in a recursive, simultaneous, and discursive manner which destroys linear methods of risk analysis and the traditional models of culture which have treated it in causal, institutional, or reactionary terms. Quite simply, we argue that the dispositions Americans and Europeans hold toward GM foods are a reflection of changes in the regulatory discourse about food safety. By elaborating upon the recursive relationships among culture, history, and political institutions, we seek to demonstrate the impor-

[1] As Somers (1995) correctly points out in her analysis of *The Civic Culture*, most studies of democracy argued whether political culture or the political system should be classified as an independent variable in a causal model. Such studies did not recognize that economic development was actually taken as a given and exogenous independent variable. In turn, such approaches were weak since ''the causal analysis is inscribed in the concept itself, or ... the independent variable (social system) is inscribed at the outset in the intervening (political culture) and dependent variables (democratic stability) (122)''.

tance of recognizing how cultural contexts can be important for understanding policy.

3. The United States' culture of economic progress

In September of 2002, the USDA levied a quarter-million-dollar penalty against a biotech company for allowing genetically engineered corn to contaminate adjacent conventional soybean fields in Nebraska. Although the incident put a scare into the biotech crop industry, like other American problems with genetic agriculture, the regulatory culture of the USA remains sanguine about the probable risks of modern farming. Despite the 1999 World Trade Organization (WTO) protests and 2000 reports that genetically engineered Bt corn not approved for human consumption was in the domestic food supply, the USA's regulatory regime of GM acceptance has never passed a single law specifically addressing food biotechnology. This is partially due to the political discourse of GM food acceptance that was created at the invention of recombinant DNA technology. In 1986, before a single genetically modified food product was commercially available, leading agricultural biotechnology companies lobbied the federal government to develop the multiple agency regulatory design called the ''Coordinated Framework for Regulation of Biotechnology'' (Guehlstorf, 2004). Biotech companies reasoned that if they had noticeable oversight and supported regulations by the USDA, EPA, and FDA, the public would have confidence in the new scientific products and processes (Guehlstorf, 2004).

As a consequence of the controversy surrounding America's first commercial genetically modified food in the early 1990s, the biotech industry abandoned its commitment to policy inclusion and lobbied the federal government for a strategy of policy exclusion—a decision that many company executives now describe as a mistake (Shapiro, 2000).[2] During this new industry strategy of privatized scientific discovery of the mid 1980s the first genetically engineered Bt corn, was field tested for efficiency against target Lepidopteron pests, including the European Corn Borer, Southwestern Corn Borer, and when toxins are expressed sufficiently in the corn ears, Army Corn Earth Worms (NRC, 2002, p. 145). This research was developed under the notion that deregulation of commercial plants could shield industry from incidents that could impair the development of transgenic agriculture. The majority of this trans-genetic crop development was done in the United States by Monsanto and some of its subsidiaries, Northrup-King, Ciba-Geigy, DeKalb, AgroEvo, and Calgene.[3] Most of these biotechnology companies, along with DuPont and Aventis were combing recombinant DNA splicing with conventional breeding methods of transplanting specific antibiotic properties of corn plants. It should be noted that Burpee seeds have been mechanically bred to repel corn insects since 1902 (NRC, 2002). Additionally, the Bt toxin is a common soil bacterium that has been used by organic farmers for many years and has been a registered commercial insecticide in France since 1938 (Powell and Leiss, 1997, p. 166). Unlike Bt toxin sprays and their conventional hybrid corn seed, however, the transgenetic Bt corn crop lines are more resistant to pests and have increased yields. According to corn growers' fact sheets, Bt corn seeds are used by American farmers because it is the most cost effective and highest yield method of controlling pests when compared to: (1) crop rotation, (2) hybrid resistant varieties, (3) insecticide treatments, and (4) releases of natural enemies.

The 1991 ''Report on National Biotechnology Policy'' by the President's Council on Competitiveness reads, ''In general, to avoid unnecessary burdens on biotechnology .... Existing regulatory structures for plants, animals, pharmaceuticals, chemicals, and toxic substances provide an adequate framework for regulation of biotechnology'' (Quayle, 1991, p. 11). The USA regulatory regime aids biotech companies by not inconveniencing them with strict rules and expensive procedures for attempting to protect society from uncertain environmental or health risks. Treating modern agriculture as an economic decision with recognized cultural biases and not a scientific decision with admitted objective intentions made a significant statement about GM acceptance in the USA. The 1992 ''Regulatory Relief Program'', explains that (1) biotech foods would be tested for human and environmental health hazards by the companies producing the new products; (2) no genetic labeling by regulatory agencies or the food industry would be allowed. Identifying GM ingredients by any label is prohibited by the USA government because it may mislead or confuse the consumer about unintended effects and unscientific risks of the universally safe products and processes of food biotechnology (FDA, 1998). Monsanto, Eli Lilly, Upjohn, Aventis, Syngenta, and biotech companies who spent billions of dollars to create genetically altered organisms used in modern agriculture argued that industry testing is superior to anything the government could conduct because of the incredible operating costs involved in doing risk assessments (Barboza, 2001). Furthermore, it was argued that a self-testing approach is more cautious than a government

[2] Some argue that opposition to rBST in the USA was caused by the negative reaction to strawberry and potato plants that were bioengineered with the ''ice-minus'' bacteria. Engineered to resist frost, test plants were awkwardly monitored by environmental scientists in spacesuits equipped with oxygen masks and uneasily regulated by the EPA who declared oversight by naming frost a pesticide.

[3] Please see ''Field Test Releases in the US Information Systems for Biotechnology'' found online at the following database: www.nbiap.vt.edu. It should be referenced that Ciba-Geigy later merged with Sandoz and Novartis, the largest seed company. Additionally, Monsanto has purchased DeKalb, Calgene, and AgroEvo.

sponsored regulatory review because biotechnology industries have a lot to lose if their science is incorrect (Guehlstorf, 2004). The 1992 policy that favors the biotechnology business has essentially remained unchanged at the time of this writing.[4]

Whether the burgeoning genetic seed companies demanded regulations or requested industry freedom, the USA regulatory regime's culture of acceptance has complied. The result has been an incredible national economic success. The United States has completed regulatory reviews for 124 different products and approved more than 50 bioengineered crops for use by farmers, including: corn, tomatoes, soybeans, cotton, potatoes, canola, squash, beets, papaya, rice, flax, and chicory (Agencies, 2004). According to governmental economic reports and environmental assessments in 2000, 36% of the corn, 55% of the soybean, and 60% of the cotton grown in the USA were from bioengineered varieties and more importantly agricultural biotechnology is rapidly increasing as 145 million acres of GM crops were cultivated in 2002 (ERS, 2004; Florida, 2004). Genetically modified organisms (GMO) are in half of all groceries in the USA and agribusinesses are reporting some of the largest fiscal gains in their 30-year history. For instance, Monsanto, the second largest seed company in the world spends over $6 billion a year on crop research, development, litigation, and marketing (Ewens, 2000, p. 3). Agricultural experts also contend that large countries with policies that limit or ban the consumption of GM food products may soon have to change course, because they will not be able to grow or import enough non-biotech food to meet their needs (Barboza, 2001).

The American culture of GM acceptance can be seen in how the most negative social consequence of genetic engineering, that the newly applied agricultural technology produces fewer and larger farms, has been managed by public administrators. Once called the "Farewell to Farms" federal regulators explained that the agricultural economics of food production significantly resemble other capitalist enterprises. That is, in order to remain competitive, one must continually adopt new industry technologies, not just for short-term gains, but also to avert the long-term risk of operating at a comparative disadvantage to others in the same field that have adopted the beneficial technology. Although the USA is one of the world's largest agricultural producers, the 2000 census reveals that for the first time in American history farming was not considered a recorded occupation because the agriculture population has been reduced to less than 2% (Guehlstorf, 2004). Americans do not fault modern farming as changing the rural landscape because growing crops is not a way of life but a type of business. As such, the USA agricultural transformation of small family farms to large corporate agribusinesses is a phenomenon that occurred 20 years before the release of GM products like Bt or RR corn.

The problem of inserting questions of cultural subjectivity into the objective discipline of science and the rational study of economics is further complicated by the fact that the "American dream" is the embodiment of development of unlimited and unquestioned progress. The general culture theory of the United States is that its people have a desire for personal wealth and often accept social changes to accommodate the technological advancements that aid in offering vast individual wealth. In reference to the interconnection of objectively derived science and the subjectivity of involved risks, it has been said that "the urge for material comfort makes Americans ready to accept ... better methods in technology ... and emphasize the future rather than the past or the present" (Deibert, 1990, p. 131). The American specific culture of GM acceptance and the dynamic belief that the best is yet to come are frequent rhetorical defenses of contested technologies because, despite risks, wealth can be found in technological innovation. Notwithstanding the value Americans place on technology, there should be a concern in science for the potential harms of GM corn that can be reasonably discussed in risk analysis. However, in order to find a subjective perspective within science, one must consider science without recursive influence of American political culture. This seems impossible because science is seen as an objective investigation of the experimental progress of the material world for human knowledge.

4. The government supported biological sciences

Biotechnology by its very definition is the application of life sciences, and since its genesis has been a combined effort of scientific discovery and technological innovation. Since Boyer helped develop the recombinant DNA technique at the University of California, biotechnology has been the amalgamation of not only science and American business, but also USA politics (Krimsky, 1999). Economists argue that American development of biotechnology has been able to expand continually beyond most business model expectations because it is largely a collaborative effort by industries, universities, and governmental agencies (Falcon, 2001). While the marriage of corporations and colleges is by no means controversial[5], many observers question the advocacy position taken by the USA government with regard to the life

[4] Although the Clinton Administration required governmental review of some previously confidential industry tests, this reform was largely symbolic because companies always submitted such data under the voluntary rule. Similarly, no risk practices were affected in 2001 when the Bush Administration revised industry guidelines on food labels by making producers use common terms in order to help consumers who are highly allergic to some food ingredients (Winter, 2001). The new food labels, however, are not mandated by the FDA and do not include the identification of any genetically altered organisms that may cause adverse human health reactions.

[5] Although the relationship of biased research and corporate funding is a topic worthy of significant concern and investigation, the collaboration of business and environmental science is an accepted union.

sciences. In addition to the executive rules discussed in the previous section are legislative actions like the ''Cooperative Research and Development Agreement'' that allow government risk assessors to conduct industry tests in federal laboratories and receive royalty income for product ideas while refusing government requirements for the public documentation of findings because it may threaten trade confidentiality (Krimsky, 1999).

This culture of acceptance is important because the regulatory regime in the USA is noticeably dissimilar to the EU multi-lateral regime of regulations for monitoring and controlling genetic agriculture. The governmental support of the scientific-commercial field of applied genetics can be nicely explained through an examination of a series of USA court cases. Supplementing the federal agencies' coordinated framework for the regulatory relief of biotechnology in 1992 is the legal doctrine that seeks not to impede the new technology without cause (Guehlstorf, 2004). The government's role in developing biotechnology is seen in the legal cases that (1) circumvent environmental requirements; (2) redefine patent law; (3) limit consumer and farmer practices. For example, Starlink's petition for Bt corn Transformation Event CBH-351 was approved in 1998 despite (1) containing a newly patented ''cry toxin that has not been available commercially in insecticides''; (2) indirect environmental effects of Bt proteins were tested on honeybees and aphids, two insects that ingest low concentrations of corn pollen; (3) less than 20% of grain elevators separate non-GM corn from GM corn because all food products from whole corn to corn sweetener will not be labeled for the American consumer (NRC, 2002, pp. 142–156).

Biotechnology has revolutionized the American society in many ways. For instance, the USA regulatory regime has changed some of its current environmental, legal, and economic standards to accommodate the promises biotech offers for the future. In both the Federal District case of *Foundation on Economic Trends versus Heckler* and the Appellate Court decision in *Foundation of Economic Trends versus Thomas*, the court decided that GM field studies may have minor revisions of environmental regulations because, ''the use of delaying tactics by those who fear and oppose scientific progress'' may create a ''national catastrophe'' for the promising technology of genetic engineering (Naik, 2000, p. 16). The most prominent development of casework affecting Bt corn is found in the promulgation of the first significant case of genetic engineering, *Diamond versus Chakrabarty*. Chakrabarty was a 1980 USA Supreme Court case that allowed inventions of biotechnology to be protectively patented. However, because Chakrabarty dealt with a bacterium, it did not secure the use of utility patents for plant breeding innovations, the largest economic area of the biotech industry (Ewens, 2000). While Congress enacted some amendments to the Plant Variety Protection Act (PVPA) of 1970 to provide intellectual property rights to plant breeders, it is not as secure as a utility patent because of the historical research and crop exceptions allowed farmers. ''Unlike the utility patent statute, which allows the patentee to exclude anyone from making, using, or selling her invention, the PVPA allows a breeder's competitors to use her protected variety or create new varieties without their permission'', a legal scholar explains (Goss, 1996, p. 7). Furthermore, the PVPA allows farmers to reuse seeds for certain purposes – even for conducting research on a breeder's protected variety – without compensating the owner(s) of the biopatent (Goss, 1996, p. 7). This traditional farming practice is very complicated with RR and Bt seed lines, however.

This complexity is best illustrated by the number of recent cases dealing with patenting living organisms and plants or biopatents. In the case of *J.E.M. Ag Supply Inc. versus Pioneer Hi-Bred International Inc.* (2001)[6], the USA legal system considered the use of 17 untraditional patents for the manufacture, use, and sale of hybrid corn seeds. These hybrid corn seed products are legally considered utility patents because these technologically advanced plants do not reproduce seeds with the same hybrid characteristics. The seed supply company challenged Pioneer's unusual patent validity because corn plants – and all sexually reproducing flora – are not patentable subject matter within the scope of existing laws. The court held that utility patents may be issued for these plants because they are newly developed plant breeds that do not fall within the subject matter of the PVPA and traditional patent law—35 U.S.C. Section 101. Therefore, J.E.M. Ag Supply and other farmers who sell unconventional corn seed are in patent infringement and biopatents can be extended the same actions as utility patents.

The court has continuously given authority to companies with new seed discoveries, and therefore, changed traditional patent law and farming practices across the country. Seed companies are expected to increase their profits since farmers who use the hybrid seeds, which cannot produce true-to-type crops, need to repurchase the seed annually. Farmers cannot produce their own seeds because they have to adhere to living license agreements. This is specifically the case with GM crop lines. In the case of *Monsanto Company versus Homan Mcfarling* (2004), the USA regulatory regime questioned the legality of Monsanto requirement that sellers of the patented GM seeds obtain from the farmer or purchaser a (1) Technology Agreement, (2) license fee per bag of seed, and (3) contract that the seed be used for planting a commercial crop only in a single season.[7] Mr. McFarling, a farmer in Mississippi, bought Roundup Ready soybean seed and signed the Technology Agreement and paid the license fee for each purchase. After one crop, however, Mr. McFarling saved 1500 bushels of the patented soybeans from his harvest and then replanted the seeds. Monsanto sued him for a preliminary injunction on

[6] J.E.M. Ag Supply Inc., Dba Farm Advantage Inc., et al., Petitioners versus Pioneer Hi-Bred International Inc.: 534 US 124 decided December 10, 2001.

[7] Monsanto Company, Plaintiff-Appellee, versus Homan Mcfarling, Defendant-Appellant: 363 F.3d 1336; 2004, decided April 9, 2004.

the ground of patent infringement and breach of contract. In turn McFarling argued that Monsanto was in violation of antitrust laws, patent misuse, and the regulations of the PVPA. The holding of the United States Court of Appeals for the Federal Circuit was that Mr. McFarling did infringe the patent of Monsanto because it is illegal to replant GM seeds which have a purchase contract forbidding the practice.

Best explained by a former USDA secretary, technology will ''improve the quality of life by developing new uses and new markets for farm products, improving farm efficiency, and strengthening farm profitability . . . to remain competitive in the world market'' (Comstock, 2000, p. 141). That is, USA policy, agency regulations, and case history values and protects innovation because it offers incentives for investment in research, financial development, and promulgates the specific culture of GM acceptance. For instance, it has inspired biotech companies to render seeds sterile after one use, with so-called ''terminator technology'', or insert marker genes that identify plants' DNA strains as the intellectual property of a biotech company. While the legality of these biotech seeds is not fully understood, the outcome is predictable. This legal trend is best explained by a recent international case involving America's Monsanto. The outcome of the Canadian case *Percy Schmeiser and Schmeiser Enterprises Ltd. versus Monsanto Canada Inc. and Monsanto Company* (2004) sparked global dialogue about GM crops. Although Schmeiser never purchased Roundup Ready Canola nor secured a license to plant it, in 1998 Monsanto inspectors discovered that 95% of his 1000 acres of canola were RR plants.[8] The Supreme Court of Canada concluded that Schmeiser infringed Monsanto's patent on life forms, regardless of the fact they may have planted and reproduced themselves on his farm. This case has further strengthened genetic seed makers and their biopatents outside the United States where other political cultures and regulatory regimes have limited the exclusive rights of genetically modified seeds. This case is a huge success for biotech companies and global markets, especially for farmers in the NAFTA zone who are now restricted from reproducing and selling seeds from crops that accidentally grow on their land.

This USA regulatory regime is shocking when contrasted to the EU member state approval and precautionary principle for GM food in Europe. With the notable exception of the organic labeling system approved by the USDA, the United States regulatory regime maintains its coordinated framework of streamlining pro-biotech approvals.[9] The commercialization of the biological sciences, however, raises a myriad of questions including: (1) Can any life form be patented? (2) Is it possible to find equilibrium between farmers who grow crops and multi-national corporations that hold the patents to those same crops? (3) Will an increase in the use of GM crops contribute to the decline of genetic biodiversity (Ewens, 2000)? The solution for all of these questions can be located in the specific American culture of regulatory regimes and not in the scientific determinations of risk analysis. That is, even if the above questions have some merit and ''biopatents are disrespectful of life, misconstrue the nature of biotechnical innovation, and render inappropriate desserts for such innovation, the tremendous social utility of biopatents outweighs these considerations'' (Hettinger, 1995, p. 11). In policy debates over the above questions, therefore, one must simply state: if Europeans want pest free corn or herbicide resistant maize they must follow the American design of allowing scientists to patent these innovations and sell them in the market.

As the human population continues to increase while the amount of arable land continues to decrease, many experts contend that food biotechnology is the best solution because it can feed more, better, and with less use of finite resources. Advocates argue that not only is biotechnology needed in the future, it minimizes the impact of agriculture on the environment when compared to current policies. Proponents maintain that, ''[b]y reducing dependency on chemicals and tillage through the development of natural fertilizers and pest-resistant plants, biotechnology has the potential to conserve natural resources, prevent soil erosion'', improve waste treatment practices, and ''offer new ways to use renewable resources for materials and fuel'' (McGlouglin, 1999). For instance, the USDA has convincing statistical data that explains that two million fewer pounds of insecticide were used in 1998 than 1995 because of the use of genetically modified corn. In fact, all three major USA federal agencies – the USDA, EPA, and FDA – have released documentation that food biotechnology will use fewer high-risk practices by replacing expensive and toxic chemical inputs with expensive, but apparently, benign genetic information, while enhancing food quantity and quality.[10]

5. GM product regulation in the European Union and Europe

Since the mid-1990s, products and foods created from genetically modified organisms have been regulated within both the European Member States and the institutions of the EU. This regulatory system is built around a system of multi-level regulation and governance, and the presence of both

[8] Monsanto Canada Inc. and Monsanto Company (Plaintiffs) versus Percy Schmeiser and Schmeiser Enterprises Ltd. (Defendants) Supreme Court of Canada, and W. Andrew MacKay, a Federal Court Judge, Ottawa, Ontario, Canada, March 29, 2001 accessed online from http://decisions.fct-cf.gc.ca/fct/2001/2001fct256.shtml on November 8, 2004.

[9] The USDA's first proposed definition for organic food included irradiated, genetically engineered, and grown with sewage sludge fertilizer. According to some environmentalists, because the notice and comment procedure received over 200,000 complaints the USDA's final definition did not include irradiated, engineered, or sewage fertilized food.

[10] See Federal Register (1992), FDA (1995) and read the Congressional Research Service Summary, June 02 1999. ''Food Biotechnology in the United States: Science, Regulation, and Issues''.

national and EU comitology-based approval systems (Hervey, 2002). Furthermore, the EU has adopted the precautionary principle (COM, 2001, p. 1) as a guiding concept, which in theory regulates biotech processes, rather than products. A number of the Member States and environmental groups have also been a driving force behind this process-based approach, leading in 1998 to a de facto moratorium on new approvals of GM-products by the EU.[11] While there was practically no EU regulation of biotechnology in the 1980s, there has been a steady progression toward very strict regulation of both GM-foods and crops, and by 2000 a substantial labeling requirement for GM inclusive products.[12] This was followed by a labeling scheme that is applicable to all products produced in which GMOs can be detected (European Commission (EC) regulation no. 50/2000), even if not traceable or apparent in the final product (Bernauer and Meins, 2001). It is our argument that this progression toward restricting the presence of GMOs in the European food supply can best understood within a regime of specific cultural and institutional context.

The attempts by the EU to create a harmonized set of GMO regulations that are consistent with the goals of the single market have both created, and responded to, the cultural orientations of Europeans toward not only the institutions and practices of the EU. The tendency of the European Commission to approve the release of GM products, and the procedures by which these decisions are reached, have led to a basic failure by the EU to regulate GMOs in a satisfactory and harmonized fashion. This is what led to the 1998 moratorium. Additionally, public dissatisfaction with the capacity of the Commission to safely manage the potential risks of GM-foods led to individual Member States adopting their own regulatory schemes. That is, the increasing publicity accorded to food and environmental scares across Europe contributed to considerable public skepticism about GM-foods, a mistrust of government, and EU legitimacy, and created what some authors refer to as a ''culture of fear'' (Rippel, 1998; Vogel, 2001).

In the mid-1980s, the EU began to regulate GMOs and their use within three areas of authority mandated by European treaties: harmonization, the environment, and agriculture. Concerned with the potential hazards of GMOs, in 1986, the European Commission proposed a framework for the regulation of GMOs both in the laboratory and released into the environment (COM, 1986, p. 573). This proposal noted the transboundary nature of micro-organisms and that ''nothing short of community-wide regulation can offer the necessary consumer and environmental protection'' (para 7.8). In 1990, the European Council adopted Directive 90/219/EEC (GMOs in laboratories) and Directive 90/220/EEC (Deliberate Release Directive). Their purpose was the harmonization of national laws on the deliberate release of GMOs into the environment for the purposes of research, development, and the eventual release of GM products onto the common market.[13] These directives also established the procedure by which GM products could be placed on the market (part C of Directive 90/220/EEC). This is a multi-level procedure of notification, concerning both national level authorities and the European Commission, in which both the Member State of application and other states participate. This was an attempt to ensure that any GM product licensed in one Member State could, in fact, be marketed in all Member States. Upon receipt of notification from a manufacturer or importer of a GM product by the appropriate national-level authority, that same authority may either forward the dossier to the Commission with a favorable opinion or inform the applicant that it has been rejected. The European Commission is then required to forward the dossier to the appropriate authorities of all Member States, and if no objection is raised within 60 days, consent to the release in the original state, and then onto the European market, could be given (Hervey, 2002).

If, however, an objection is raised, the issue must be transferred to a comitology procedure at the EU level (Article 21 of Directive 90/220/EEC). This procedure consists of a regulatory committee composed of representatives from the Member States and chaired by the Commission. The Commission is then to draft a committee decision, which has to date always been to propose authorization, for the committee to decide based on a qualified majority vote as outlined in Article 148(2) of the Treaty of Rome. If the committee chooses not to adopt the proposal, the Commission is required to submit the proposal to the Council, who may in turn either pass it by qualified majority, or reject it by unanimous decision. The Council may also choose not to act, in which case after 3 months have passed ''the proposed measures shall be adopted by the Commission''. (Article 21 of Directive 90/220/EEC) As a result, in many ways the Commission is the final seat of real decisionmaking authority regarding the release of GM products (Hervey, 2002). Not only does the Commission chair the comitology procedure and draft the measures under consideration, it may also determine the implementation of such measures. Unless the Council unanimously rejects the measures, which is inherently difficult, the process is oriented toward both the Commission and the approval of GM products.

The Commission will often seek reports from various scientific sources and committees in order to better assess the risks associated with a specific GM product. However, these sources need not, and have not, always considered the risk elements considered germane by either the Council or the committee. While the derogation Article 16 of Directive 90/220/EEC allows Member States to restrict or prohibit the

[11] Only the UK, the Netherlands, and the EU Commission opposed a formal moratorium.

[12] Commission regulation no. 49/2000 requires labeling of a product if at least 1% is genetically modified.

[13] This Directive has now been repealed and replaced with Directive 2001/18/EC OJ 2001 L 106/1 and Commission regulation (EC) no.641/2004.

sale or use of a GM product where ''justifiable reasons'' existed, it permits only a 3-month respite. This process, especially after the Bt maize case, has been identified as containing a number of legitimacy issues (Hervey, 2002). Not only does the procedure raise doubts as to the viability of citizen input into GM regulation, but it places the European Commission, a relatively small, under-funded, technocratic, yet information poor administrative body, at the heart of GMO regulation. In addition to the traditional problems of the ''democratic deficit''(Andersen and Eliassen, 1996; Wallace and Smith, 1995) faced by the Commission, the deliberations of the EU-based bodies (the Commission, the Council, and the Regulatory Committee) all take place ''behind closed doors'' (Hunter, 1999, p. 225).

Ultimately, this combination proved unworkable. Faced by issues of legitimacy and accountability, in late 1997 the Commission and Council began to issue a number of additional regulations, as well as revisions to Directive 90/220. These regulations (EC) no. 1139/98 and (EC) no. 49/2000 were intended to address the perceived failures of the Novel Food Regulation. This meant including GM soybeans and maize approved prior to 1997 and addressing the failings of earlier legislation by introducing limited conceptions of risk assessment, defined time limits, a simplified approval process, and increasing transparency in decisionmaking (Rosso-Grossman and Endres, 2000). In April 2000, the European Parliament approved a draft accepting compromises on the environmental conditions noted above[14], and in July 2001, the European Commission proposed a regulation of the European Parliament and Council that would amend Directive 2001/18 in order to account for the possibility that ''differences between Member States' provisions concerning traceability of GMOs and derived food and feed products may hinder the free movement of products, creating conditions of unequal and unfair competition'' (Europa, 2001). Although this proposal sought to establish a harmonized framework for the traceability of GMOs, instead it seems to have further contributed to a public atmosphere that is not favorable to GMOs and resulted in the moratorium.

What is not made apparent from the above discussion is how this can be understood within a specific cultural context, and in turn how such cultural factors can contribute to our understanding of how this regulatory environment evolved. The following section examines this cultural component. It focuses on how the increasing stringency of EU and Member State regulations for GMOs have coincided with (1) a crisis of legitimacy for EU institutions and policies; (2) the end of ''permissive consensus''; (3) increasing skepticism of EU decisionmaking, particularly when it comes to food safety. This is, of course, in part a reaction to a number of food crises in Europe during the 1990s such as BSE, dioxin contamination, and hoof-and-mouth disease, but these should be considered as part of a larger trend in the political cultures (for it is not yet appropriate to speak of a European political culture) of European states. Although we argue that these changes are the result of multiple interacting factors, it is important to note that the public reaction to GMOs in Europe, and particularly of environmental organizations, is consistent with the pattern of environmentalism on that continent (Caldwell, 1990; Dowie, 1995; Gottlieb, 1993; Lipschutz, 1996; Merchant, 1993).[15]

In contrast to the 120-year-old environmental movement in the USA, which hinged on the ''commodification of nature'' in shaping environmental activism and policy (Harvey, 1996), European environmentalism has focused more upon industrial risks (Harper, 2003). As Strydom pointed out, since the 1970s environmentalists in Europe (and particularly the UK and Germany) saw nuclear energy, waste, and contamination as the primary technological threats to public health and environmental quality: ''names such as Marcoule, Gorleben, Windscale/Sellafield, Harrisburg, and Chernobyl were regarded as the most embittered social conflicts in advanced modern history'' (Strydom, 2002, p. 33). Having no comparable history to the American experience of colonial settlement, expansion, and the perception of unlimited resources, the European variant of environmentalism has focused on the connections between health and the environment. In contrast, American environmentalism has emerged with a predominant focus on resources, scarcity, and resource management. The early conservationist policies in the USA are indicative of this and even recent issues like non-point source contamination of agricultural water supplies focuses less on environmental quality and human health than managing issues of scarcity and maintaining the sacred or sublime American nature-escape (Harvey, 1996, p. 7).[16]

These two broad trends are further reflected in the specific approaches taken toward environmental policy in the EU and USA, which, as Backstrand (2002, p. 1) points out, can be understood within the context of three models for technocratic environmental decision-making: precaution, scientisation, and deliberation. The precautionary principle is an attempt to provide a procedural guide for decisionmaking under ''conditions of scientific uncertainty, large decision stakes, controversy, and risk for ecological irreversibility'' (Backstrand, 2002, p. 9) and has become one of the central principles of international, and European Union, law. The principle is noted in the Treaty of the European Union and the 1992 Rio Declaration, and is a way

[14] No new GMO products were approved under Directive 90/220 after October 1998, and to date none of the 12 under application has been passed under the new Directive (Annexure 1 of the 1990 Directive). In fact, the tendency of certain member-states to pass their own regulations regarding GMOs has continued to be an issue for the EU, particularly in terms of the free movement of products.

[15] This is a highly limited and superficial comparison of European and American environmentalism. Nonetheless, please note the difference and reference the above authors for greater detail.

[16] Although there are significant exceptions to characterization, there is no specific example of GM environmental activism based on recognizing connections between the environment and human health in the USA.

to institutionalize prudence, precaution, and a bias toward safety, rather than innovation and risk. This again is demonstrative of a larger gap in the environmental policy milieu of the European Union and member states, versus the USA. While the EU does invoke the precautionary principle as a guiding theme, the USA falls more in line with scientisation—relying upon science to identify, characterize, represent, and ultimately solve environmental problems. The USA position is that the EU stance on GMO regulation is largely political and should be more scientific, based on risk-benefit analyses. It is our argument that because both regimes recursively interact with political culture, the intersection of science and environmental policy is radically dissimilar. This interaction is important when examining the specific issue of GMO regulations and discursive patterns of environmental concern and management.

In the EU, this larger trend is the result of a number of factors, including the negotiation of the Maastricht Treaty and the shift toward both an enlarged European Union and greater political integration. It includes an increase in the public awareness of, and dissatisfaction with, the institutional, functional, and civil deficits of EU-governance. There is also concern with the time lag of GMO-regulation created by still-developing multi-level governance, and the largely technocratic, pro-science tendencies of the European Commission. This has, in turn, contributed to the ''culture shift'' regarding food safety and the decision by five Member State governments to invoke the derogation clause (Article 16 of Directive 90/220/EEC)[17], and ultimately the June 1999 decision by the Environment Council in Luxembourg to begin the moratorium noted above.

This shift hinges on a fundamental challenge to the value assigned to objective science and rational administration by the European Union. We argue that the EU is perceived as having failed to meet the three objectives of risk management, and that the previously neutral public perception of the EU as an administrative presence has disappeared. Instead, the process of EU-level risk management has been exposed as a highly political practice. This has reduced the capacity of the EU as a legitimate regulatory actor, and has created a conflict over what values should drive the process and regulation of genetically modified foods. These events, combined with considerable media attention to genetic technologies and the associated ethical consideration concerning cloning, stem cell research, and GM foods, have raised concerns among European consumers over institutional, policy, and governance-based legitimacy (Gaivoronskaid and Solem, 2000). In order to demonstrate this, we conclude with a case study of the Bt maize case in Europe.

[17] When Directive 2001/18 came into effect in October of 2002, Article 23 (Safeguard clause) permitted temporary bans of approved products. The derogation clause of Directive 90/220 has been evoked eight times, and none of these national bans have been overturned (Schweiger, 2001).

6. The end of ''permissive consensus'' and food as a discourse of failure

Prior to the ratification of the Maastricht Treaty, a crucial assumption held by the political and policy elites driving integration and the creation of the ''would-be polity'' was ''permissive consensus'' (Liebert, 2001). From this perspective, integration elites could exercise considerable discretion in their activities and the exercise of governance. Public opinion toward the EC was seen as a passive condition for elite activity, providing neither an impetus nor barrier to the economic and later socio-political changes required by integration (Liebert, 2001). However, as the political scope of the EC began to expand in the mid-1980s, so too did the erosion of the ''permissive consensus''. By the early 1990s, popular support for the EU had declined substantially, public concern over the ''democratic deficit'' had grown, and Euroskeptic movements had mobilized mass national constituencies to vote against membership in the EU.[18] Events such as the Inter-Governmental Conferences (IGCs) in Amsterdam and Nice were a reflection not only of the political weaknesses of the Maastricht Treaty, but also of a cultural change in how many Europeans viewed the institutions and practices of the EU (Petite, 1998).

This shift away from permissive consensus is important for our understanding of the GM food regulatory regime in the EU. It was indicative of a larger political shift in Europe, and the various European publics' understandings of political integration. As Liebert (2001, p. 5) writes, ''This transformation of mass public attitudes indicated a shift in European integration from a neo-functionalist or intergovernmental elite driven project to a contested, politicized process of Europeanization''. As the institutions and practices of the EU gained political authority they declined in political legitimacy. The combination of media attention, occasionally bizarre regulations, multi-level governance, and the absence of many structures for citizen input contributed to an increase in the degree of controversy and uncertainty associated with political integration (Ray, 1999).

The combination of comitology structures and a preference for science, while attempting to create a harmonized system of risk assessment, actually compounded the extant culture shift toward skepticism of EU-regulation of foods. The changes in the political discourse of the EU in the early 1990s have been reinforced by the various food crises, the continuing series of treaty negotiations and institutional reforms, and the continued willingness of the EU to promote science over alternative views. The reform-oriented referenda that were intended to make the EU more ''democratic'', de-centralized, and effective, added to the legitimacy issues already present as a result of the ratification of Maastricht. While this may prove only slightly detrimental in certain ''high'' policy areas such

[18] Denmark in 1992 and 1993, France in 1993, and Austria, Sweden, Norway, and Finland in 1994.

as the actual negotiations of the IGCs and treaties, it is problematic in areas such as GM-foods. We argue that the attempts of the EU to effectively regulate GM food, and the institutions designed to facilitate this regulation, prompted levels of public outrage that built upon a pre-existing discursive change (Hervey, 2002). While the EU as a regulatory actor has consistently relied on science and technology in its management of the risks associated with GM foods, this consistency pre-supposed a certain position of power in that discourse of risk that has proved false. Specifically, the comitology procedure, and the failures of the scientific committees involved, attempt to guide regulatory policy in a continued state of permissive consensus. However, at both EU and Member State levels, there is now a highly contested political arena surrounding environmental and regulatory policy, As a result, at the public level, while the shift in the locus of power was not new, the opportunities to identify and critique this claim to power were. In turn, the political aspirations of integration initiated in Maastricht were countered, particularly in terms of food, by the failure of the EU to effectively demonstrate the legitimacy of its claim to power.

We, therefore, argue that while the EU has moved from a position of no regulation for GM-products to increasingly stringent policies, it should not necessarily be interpreted as a difference in the content of the dominant discourse of rational science. Instead, the progression to de facto moratorium is an indication of how culture, as a set of relational meanings and discourses, has interacted with institutions and actors to affect regulatory outcomes. The discourse over the safety and desirability of genetically modified foods in Europe, in contrast to the USA, has been moved away from a reliance and faith in ''science'' because the institutions and actors attempting to wield that discourse did so without recognizing their diminished position. Not only did the end of permissive consensus place the EU under increased public and political scrutiny, but also as GM foods became a political issue, the EU proved unable to manage and maintain a position of privilege. The political questions of design and purpose led to increased demands upon the EU's legitimacy as a body capable of managing risk. This, in turn, provided an opportunity for national governments to challenge their perceived loss of sovereign authority and the position of the EU in the evolving system of multi-level governance.

7. The "maize" of European regulation: a case study in complexity

While demonstrated to improve corn borer resistance and productivity, Bt maize has raised concerns in Europe about the safety of genetically modified products, and in particular the effects of Bt toxins on non-targeted species such as the Monarch butterfly. These concerns, and the ability of environmental groups such as Greenpeace to capitalize on both legal opportunities and public sentiment, contributed to the eventual moratorium on GM products. In a larger cultural sense, the Bt maize case demonstrates the issues arising from the complexity of the European regulatory and approval process, and the policy implications arising from the interplay of European and national-level institutions, the comitology procedure, and non-governmental actors. As a result, the story of Bt maize in Europe captures the tension and interactions between science, culture, and multi-level governance that resulted in the de facto ban on GM products.

The Bt maize issue emerged in Europe in 1996 with the application of a French-based division of Ciba-Geigy under EC Directive 90/220 for the release of genetically modified Bt maize as the first plant with a genetic ability to protect itself from the European corn borer (BNA, 1996a).[19] Only the third genetically modified agricultural product to be reviewed by the EU, this maize seed was denied approval by the Article 21 Committee, despite earlier approval by the Commission's Directorate General XI (Environment). As a consequence of insufficient labeling and the possible poisoning of certain insect larvae, the Committee was unable to reach the qualified majority required for approval (BNA, 1996d). According to Directive 90/220/EC, if the Article 21 Committee rejects the proposed release (as in the Bt maize case) or fails to deliver an opinion, the Commission is required to submit the proposed release to the Council of Environmental Ministers. The Council must act, again by qualified majority, within 3 months. Failure to do so permits the Commission to adopt the proposal, and in this case, the meeting schedule of the Council, combined with the June 1996 decision to return the issue to the Commission, resulted in the Commission becoming the final determinant of approval. It was at this time that the debate regarding both the science surrounding the proposal, and the effects of Bt maize, came under question in Europe (specifically in Austria), and the controversy began to affect EU-level bodies (BNA, 1996b).

In July 1996, the Commission postponed its decision on genetically modified maize to include the findings from three scientific committees. An Austrian study, released earlier that month, pointed to the difficulties of effective long-term risk assessments outlined in EU Directive 94/15/EEC (Adapting to Technical Progress for the First Time Council Directive 90/220), and argued that because such methods are usually based on studies of traditional, non-GM crops, it is difficult, if not impossible, to infer the absence of adverse effects in genetically modified products. The director of that project, Helge Torgerson, noted that ''the assessment criteria is not really relevant ... real risk assessments should be concentrated on issues such as changes in agricultural practice ... climate change, water pollution, and toxic effects on humans, animals, and other organisms'' (BNA, 1996c). Although methodological doubt

[19] This seed had been approved by the United States of America, Japan, and Canada in 1995 (BNA, 1997b, Jan 8).

and uncertainty contributed to the Commission's decision, it was really the product of multiple factors. In May of 1996, the Austrian government declared a 2-year moratorium on the deliberate release of GMOs, and increasingly vocal opposition from environmental groups led DG XI Commissioner Ritt Bjerregaard to say ''In the light of the widespread political and public concerns raised in relation to this proposal, I find it necessary that we do our utmost to ensure that the basis for assessing the effects on human health and the environment is as broad and scientifically solid as possible'' (BNA, 1996b).

As food and crop biotechnology moved onto the European political agenda, Greenpeace, Friends of the Earth, and the Third World Network opposed the release and import of GM products in the EU. These groups also attempted to generate demand for new biosafety protocol to govern biodiversity and safety, despite industry arguments that the United Nations Environment Program's (UNEP) biotechnology guidelines were more than sufficient. There was, therefore, a nascent collection of NGO and public concern about GM foods in certain areas of Europe by the mid-1990s (Eurobarometer 58, 2003). French, Austrian, and German branches of large, multi-national NGOs such as Greenpeace at this time were already trying to mobilize consumer attention and boycott GM products such as RR soybeans, and while public knowledge of biotechnology remained low throughout the remainder of the 1990s, public concern about the health and environmental risks started to grow (BNA, 1996c).

Based on reports from the three scientific committees the European Commission voted in December of 1996 to approve the use of Bt maize and maize seed. Having reviewed both the Austrian report and the original environmental impact assessments, the Commission based its decision on a number of conclusions. These included claims that there were: (1) no reasons to believe Bt maize would have adverse effects on human or animal health; (2) certain herbicides would be limited on GM maize; (3) insect resistance to Bt toxins could not be considered an adverse environmental effect, as pre-existing means of insect control were still available (BNA, 1997b). Despite this approval, based again on Article 16 of Directive 90/220/EEC, in February of the same year Luxembourg joined Austria in banning genetically modified foods. Citing the failure of the Commission to wait for long-term risk assessments of Bt maize, the Austrian and Luxembourg bans forced the Commission to reinitiate the scientific evaluations of the maize. These raised serious questions about the functioning of the single market in Europe and contributed to the trade dispute between the EU and the USA (BNA, 1997a). Later that year, Italy joined the ban on Bt maize, again citing Article 16, and while Industry and Trade Commissioners Bangemann and Brittan supported the easing of trade restrictions on GM foods, Environment and Consumer Commissioners Bjerregard and Bonino opposed such a step, and proposed new labeling requirements for all GM foods (BNA, 1997b).

In September of 1997, the EC approved a regulation requiring the labeling of foods produced from GM soybeans and maize as part of an attempt to increase ethical considerations in the approval of GM foods. Based on additional provisions for the introduction of novel foods (Article 8 of regulation (EC) No 258/1997), this was part of a larger strategy by the Commission to sidestep a possible trade dispute with the USA[20], address public concerns about food biotechnology in Europe, and improve the probability of actually putting genetically modified maize back on European markets. At the same time, both Luxembourg and Austria continued to defy the European Commission's request that they end bans on GM-maize (BNA, 1997c). This would lead to continued legal action involving the French *Conseil d'Etat* (Council of State), the European Court of Justice, and both national and international environmental groups. Additionally, legal battles over regulatory jurisdiction further contributed to the complexity of the European regulatory regime, and the rising levels of public awareness, skepticism, and concern regarding genetically modified foods (PABE, 2001).[21]

The ''Public Perceptions of Agricultural Biotechnology in Europe'' study funded by the Commission presents a number of findings that are relevant to this study, as they reinforce the importance of institutional assessment in the EU. This study also demonstrates that public understandings and perceptions of new technologies, such as GMOs, include not only an institutional component, but also a cultural component to the policy responses to GM-maize. This is important because, as the PABE report points out, ''mistaken interpretations of public perceptions play an important role in shaping ... policies of decision-makers ... New policies and strategies ... are likely to fail if they continue to be based on these entrenched views'' (PABE, 2001, p. 7). The primary findings of this study conclude that culture does matter to regulatory policy, and in particular it is argued that unless the perceived legitimacy and efficacy of European regulatory institutions are improved, a ''more constructive and satisfactory debate on agricultural biotechnologies in Europe'' (PABE, 2001, p. 7) is unlikely to emerge. The PABE report identifies a number of socio-cultural elements that underlie public responses to biotechnology.

Although space does not permit a detailed analysis of this extensive project, a key factor relevant to this study is the identification of a different kind of knowledge used by the lay public to assess agricultural biotechnology. Collected from focus groups conducted in multiple European states, Europeans demonstrated: (1) non-specialist knowledge about 'natural life'; (2) knowledge of human fallibility;

[20] At this time, the regulation did not require forced segregation of GM crops from traditional crops. US officials had indicated to the EU that any such segregation would probably result in a trade dispute.

[21] This is demonstrated by the massive surge in public opinion regarding genetically modified foods in France after 1996. Essentially, France moved from being a state with practically no public opposition to GM foods, to a leading anti-GMO body in Europe.

(3) experience of past institutional actions. In particular, the report points to a continuing decline in levels of European trust in expert and regulatory institutions, due in part to the knowledge and the process on which these institutions have relied. Not only did focus group participants recognize the inherent uncertainties present in the GM-agriculture and food issue, they were particularly troubled by the failure of expert institutions to acknowledge those same uncertainties. This failure, and the corresponding lack of trust in those same institutions, is related to public concerns with transparency, accountability, limited forms of expertise, equity issues, and social need regarding GMOs (PABE, 2001, p. 87). These concerns, and the fact that Europeans engage in a rather complex and nested analysis of the risks, costs, and benefits of all genetically-modified events, point to the need for a much more sophisticated understanding of how culture, institutions, and science interact to shape policy outcomes.

These interactions are exemplified in the second phase of the Bt maize controversy in Europe, which began in November of 1997. At this time, France announced that it would permit farmers to use the same genetically modified maize seed that triggered the comitology procedure (Franks, 1999). However, the French government simultaneously announced a moratorium on the ''introduction, production, or sale of all other GMOs'' and ''vowed to put in place a biovigilance mechanism under joint control of the Ministry of Agriculture and Ministry of Environment'' (BNA, 1997a). The product of ministry-level concern in France with health and safety, the French decision was based primarily on the findings of the Commission a year earlier, but despite claims of no risk, French environmental NGOs were critical of both the move and Prime Minister Lionel Jospin, who had promised prior to election to block authorizations of GMOs.[22]

This release was further complicated on September 25, 1998, when the *Conseil D'Etat* struck down the approval in response to legal challenges from Greenpeace and Ecoropa. As the highest arbiter of governmental decisions in France, the *Conseil* overturned the 1998 decree on the basis of a failure to fully include the precautionary principle, and the failure to follow French legal procedure in entering Bt maize into the French Official Catalogue of Cultivated Plant Species. Although both the French Ministry of Agriculture and Novartis defended the administrative procedures and approval process of the seed, Greenpeace counsel argued that since Novartis presented technical documents on the product in English (rather than French) and the opinion was issued from an authority despite the related resignation of its director, the decree should be struck down (BNA, 1998). This proved to be yet another complication for the Commission's campaign against the Austria and Luxembourg bans, and the approval of other variants of Bt maize, as it further contributed to both public opinion and legal uncertainty[23] regarding the regulation of GM crops. Ultimately, these challenges led to the *Conseil d'Etat* request that the ECJ determine the Court's obligation to follow the Commission's rulings, and further legal battles between France and the Commission.[24] Based again on procedural issues, and compounded by continuing debate over the validity of the science involved in the Bt maize approvals, 1999 saw a series of legal initiatives, administrative proposals, and in turn, calls from Greece and later France for a Europe-wide ban on all GMOs that remains in place to this day (Douguet and Martin, 2003).

8. Conclusion: risk analysis of modern agriculture in cultural perspective

In 2003, the USA, Canada and Argentina launched a World Trade Organization (WTO) case against the European Union for its 1998 de facto moratorium on new approvals of GM food varieties. The legal argument for USA, Canada, and Argentina is based on the WTO mandate that the EU must provide strong scientific arguments for its moratorium. Although not part of this study, it should be noted that Mexico has also banned GM maize cultivation with little environmental or human health concerns and instead focuses on the management of the socio-cultural risks of GM maize. Specifically, Mexico contends that risk assessments carried out in the United States are not adequate to determine potential impacts in Mexico. This is important because risk management has three objectives: ''(1) reducing risks by reducing the probability of the occurrence of adverse events, (2) spreading risks across a group such that particular individuals or subclasses are not inequitably subject to non-compensated risk, and (3) allocating responsibility for compensation to those producing risks''(Sergerson and Bromley, 1985, p. 101; Thiele, 2000, p. 544).

In both the USA and Europe, there is a significant difference between the exacting scientific standards of evidence for risk assessment and the less demanding standards used for predicting regulatory estimates of harm in the same evaluation. For example, although the science used to determine the levels of carcinogens in a food additive is very sophisticated, the scientific probabilities about the amount of the additive to be consumed by healthy populations in the final risk characterization reviewed and reported by government are not. Thus, there is a significant difference between using risk analysis as a scientific practice for decisions and as a political tool to legitimize decisions (NRC, 2002). Regardless of suspect methodology and

[22] The first approval had been submitted under the Chirac-led Gaulist Party. However, Jospin's government consisted of a left coalition led by the Socialist Party, and was less favourable toward GMOs.

[23] The court's decision raised further legal challenges to other maize types: herbicide resistant TER 25 and MON 810, another maize resistant to the European corn borer.

[24] The ECJ ruled that a French court of civil law cannot overrule an approval taken by the EU (ECJ C6/99).

limited scientific data, scientific regulators are under pressure to determine the uncertain long-term effects of new products and processes with limited data on the short-term effects between environmental alterations and public health. As a consequence, risk is often culturally based, which includes science, but is not limited to that discipline.

A dominant theme of all cultural work in risk theory is that regulatory regimes are analytical constructs; although they can be described to infinite levels of complexity, they are not inherently observable by all policy actors (Hood et al., 2001). As we argued in this paper, however, in offering a comparative view of a single genetically modified product between two culturally dissimilar regulatory bodies, we have drawn distinctions in order to demonstrate that culture can be identified as something between a single causal essence and a list of abstract features. This scholarly advance is noteworthy because it should offer some insights into current public debates about genetically modified organisms and provide a better framework for understanding how the context of regulatory politic may affect the content of a regulatory policy. For instance, with our view of risk one could state that the American regulatory regime is not open to environmental democracy because it is as an aggressive economic system with elite social and political goals, that must maintain the dominant positions of no consumer labeling and only industry safety testing of GM foods in order to control USA and Canadian markets. Additionally, if the EU can recover from the crises of legitimacy during the 1990s and affect a culturally-oriented return of trust in both EU regulation and science, it is possible for the EU to release the ban on all genetically modified foods and fulfill its goals of economic integration.

While many risk scholars have discussed the ''various sorts of uncertainty and value-commitments'' that enter the scientific decisionmaking of environmental and human health hazards, recognizing culture may improve the conduct of risk management (De Marchi and Ravetz, 1999, p. 744). As Cranor (1990, p. 126) writes, ''the supposedly objective scientific studies used for estimating risks to human health for regulatory purposes can be considerably more controversial and political than most people think''. Put simply, there can be substantial differences between the rational-science standards of evidence for risk assessment, and the less demanding standards used for generating estimates of harm in the same evaluation. There is, therefore, a long-standing recognition of the inherently political nature of risk and regulation, and this culturally based examination gives an insight into this nature. It does so by illustrating how culture, if understood as a relational set of meanings can be used as a way of discerning the politically motivated framing of risk assessment as an objective procedure. In turn, it is a way of furthering our understanding of regulatory outcomes as a part of that framing discourse. By recognizing that the discourse or culture of GM food in the USA and EU hinges around the capacity to control or limit the ethical, moral, or epistemological content of risk assessment, one can begin to understand risk management as a function ''intentionally biased in order to produce certain public policies and regulatory rules'' (Cranor, 1990, p. 125). For it has been said, ''A mutual awareness of the structure of relationships of trust among participants in the complex processes of risk management is therefore important for its effective operation'' (De Marchi and Ravetz, 1999, p. 743).

In the case of the EU, we believe that the regulatory policies that have arisen since the mid-1990s should be understood as a result of a cultural struggle over both the values associated with rational science and regulatory trust. In essence, the combination of institutional factors, political history, and a broad cultural ''shift'' in the early 1990s contributed to a change in the value assigned to the exercise of ''objective'' science by political institutions. Similarly, the economic and commercial pressures that the United States demonstrates when vigorously promoting GM agricultural exports during WTO meetings reveal a subjective management of free markets, and not the objective science of public health and protection of the environment (De Marchi and Ravetz, 1999, p. 749). By explaining these cultural differences as elements of a regulatory risk regime, we have exposed the value-laden nature of the use of risk assessment in regulatory practice, in contrast to the assumption of objective evaluation. Risk analysis, despite its necessary position in contemporary public policymaking, has been criticized by both elites and citizens for its lack of scientific rigor and its failure to predict and evaluate environmental and health impacts with any real certainty. It has been stated that the ''management of human activity to minimize adverse environmental effects depends on information and understanding (Treweek, 1996, p. 196)'' about ecosystems function which is necessarily limited, yet it has often hinged upon assumptions that are taken as apolitical.

As a product of institutional, functional, and historical factors that are limited to the EU as a unique political entity, the moratorium on GM foods is an outcome derived from changes in the discourse of risk. It is a partial rejection of objective science and risk management based on that science, due to both its failures and the realization that its policies are an exercise in subjective power. This was nicely illustrated by the US risk analysis that permitted regulatory approval of Starlink's GM corn that used a commercially unavailable insecticide, contained suspect test trials and questionable industry practices.

Although having the opposite regulatory decision, the variables and methods used in the regulatory procedures of the EU risk assessment of GM maize demonstrates that the process is replete with moral and policy judgments. These are indicative of the subjective politics of risk management and the political elements of the science of risk. The dominant administrative practices in both the European Commission and the USA have been subject to an ideological bias that favours new and contested technol-

ogies (Plutzer et al., 1998). However, in contrast to the USA, this ideological bias has been challenged in the discourse of GM food in the EU. As a result, there is an increasing call from both scholars and the European public for democratic influence as a necessary condition of good policymaking (Thiele, 2000, p. 559) but as a counterpart, not replacement, to scientific and technical communication of environmental risk (Shrader-Frechette, 1985). It is the balance of power between these two factors, as noted above, that helps to shape, and interacts with, GM food regulation, and accounts for the status of such regulation in the USA and the EU. In order to serve as agents of social learning, regulatory risk regimes must have a democratic structure that allows communication and the influence of power from the public sphere, technical expertise, special interest mobilization, and respected agencies of governmental legitimacy.

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