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# Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States

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## ABSTRACT

This paper uses the contrasts between European and American policies toward the regulation of genetically modified foods as a vehicle for exploring the significant differences in European and American regulatory policies that have emerged since the mid 1980s. From the mid 1960s, through the mid 1980s, health, safety and environmental policies were more salient and more contentious in the US than in Europe. American regulatory standards were generally stricter and more risk averse and often based on the precautionary principle.

Over the last fifteen years, the relationship between European and American regulatory politics and policies has been transformed. In a number of policy areas, including but not confined to the regulation of GMOs, European regulatory politics have become more contentious and European regulatory policies more risk-averse than in the United States.

This is primarily due to three developments. One is the diffusion of public concerns about health and environmental issues from northern Europe to the rest of Europe, most notably Great Britain, Belgium, France and Italy. Second, the growing regulatory competence of the European Union has created more political space for the representation of civic interests. Third, there have been a number of highly visible regulatory failures in a number of European countries as well as the EU, which have undermined public confidence in technology, scientific expertise and regulatory authorities.

European and American regulatory policies are not converging. While few American standards developed during the 1970s have been relaxed, there have been fewer new regulatory initiatives in the US than in Europe. In addition, the areas of regulation in which European policies are relatively risk-averse are different from those in the United States.

## INTRODUCTION

This paper seeks to place the divergent approaches of the European Union and United States toward the introduction and marketing of genetically modified (GM) foods and seeds in a broader context.[1] It argues that an important key to understanding why Europe and the United States have chosen to regulate identical technologies in such a dissimilar fashion has to do with recent changes in politics of risk regulation in Europe. From the 1960s through the mid 1980s, the regulation of health, safety and environmental risks was generally stricter in the United States than in Europe. Since the mid 1980s, the obverse has often been the case: a wide array of European consumer and environmental regulations, including those governing GMOs, are now more restrictive than in the United States. In a number of important respects, European regulatory politics and policies over the last fifteen years resemble those of the United States between the late 1960s and the mid 1980s. They are often politicized, highly contentious and characterized by a suspicion of science and a mistrust of both government and industry. By contrast, the US regulation of GMOs resembles the European regulatory style of the 1970s: regulators have worked cooperatively with industry and been supportive of technological innovation, while non-governmental organizations (NGOs) have enjoyed little access to the policy process.[2]

This paper begins by reviewing comparative studies of health, safety and environmental regulation in Europe and the United States in order to place contemporary cross-Atlantic regulatory differences in an historical context. It then summarizes the evolution of American and European policies governing GMOs. The third section of the paper reviews a number of explanations for the differences in European and American regulatory policies toward this new agricultural technology, and the final section advances an explanation rooted in the emergence of a new European approach toward risk regulation in general, and food safety in particular.

## HISTORICAL CONTEXT

The extensive comparative literature on public health, safety and environmental regulation in the United States and Europe published during the 1980s reported significant differences in American and European approaches toward the management of technological risks.[3] As a general rule American regulatory politics tended to be more contentious, confrontational and adversarial than in Europe. There was less public trust in government officials and more widespread public skepticism about the benefits of new technologies. The American regulatory process was relatively legalistic, formal and open, with NGOs enjoying considerable access and influence. The decisions of regulatory agencies were politically visible and subject to extensive public review. Industry

was often mistrusted and frequently found itself on the political defensive. By contrast, in Europe, "policy decisions about risk remained (closed to the public) . . . the preserve of experienced bureaucrats and their established advisory networks."[4] NGOs had limited access to the regulatory process and public officials tended to work closely and cooperatively with business. In the United States, regulatory politics were often informed by competing representations of risk among NGOs, industry and regulators, while in Europe policy-making was more likely to reflect a scientific consensus between business and government experts.

These contrasts in regulatory politics and procedures were reflected in different risk policies across the Atlantic. In general, American regulatory agencies tended to be more risk-averse, with risks of future harm frequently assigned considerable weight, especially if the public regarded such risks as intolerable. In virtually every case for which direct comparisons are possible, American health, safety and environmental standards were stricter than in most European countries. For example, following the Federal Drug Act amendments of 1962, the American Food and Drug Administration (FDA) became considerably slower to approve new drugs than its counterparts in Germany and Britain; the result was a substantial cross-Atlantic "drug lag," with new drugs typically approved years earlier in Europe than the US.

During the 1970s, U.S. agencies designated as carcinogens a number of chemicals that most European regulators did not consider a cancer risk to humans. The Environmental Protection Agency (EPA) banned the pesticides aldrin and dieldrin, while, on the basis of the same scientific evidence, British authorities permitted their use. The toxic dioxin TCDD was banned in America while its use was only restricted in Britain. In 1989, the Natural Resources Defense Council, an American environmental NGO, waged a highly visible public campaign to ban the use of Alar, a chemical compound used as a plant-growth regulator by apple growers. Notwithstanding the lack of scientific evidence that the spraying of Alar on apples presented more than a de minimus cancer risk to consumers, the EPA was forced to ban the use of this chemical – making the US the only country in the world to do so.[5]

Ironically, notwithstanding strong American criticisms of the EU's use of the precautionary principle to prevent or delay the approval of GMOs, "no country has so fully adopted the essence of the precautionary principle in domestic law as the United States."[6] The precautionary principle in American regulation of food safety was enshrined in the Delaney clause to the Food, Drug and Cosmetic Act, which banned the use of any food additive if tests revealed that it caused cancer in either laboratory animals or humans on the grounds that such chemicals could cause irreversible harms.[7] The precautionary principle also underlay many American environmental statutes enacted during of the

1970s. Both the 1970 Clean Air Amendments and Clean Water Act required the EPA to apply "an adequate margin of safety" in setting emission limits for hazardous pollutants. Regulatory agencies were often not required to wait for scientific proof of harm before establishing standards or imposing restrictions, and in some cases were explicitly prohibited from doing so. The 1997 Clean Air Act Amendments authorized EPA to "assess risk rather than wait for proof or actual harm," before establishing standards.[8] Under the Endangered Species Act, a finding of potential irreversible harm can lead to an order to desist all development activities.

A precautionary approach toward risk regulation was also reflected in and reinforced by a number of judicial decisions. In *Sierra Club v. Siegler*, the Court interpreted the environmental impact requirement of the National Environmental Policy Act as requiring a worst-case analysis on the grounds that it was needed "to assist decision making in the face of scientific uncertainty."[9] In a 1976 Court of Appeals decision upholding EPA's ambient air standard for lead, the court reasoned: "A statute allowing for regulation in the face of danger is, necessarily, a *precautionary* statute. Regulatory action may be taken before the threatened harm occurs. . . . the statutes and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable"[10] (italics added). In *Reserve Mining*, the Supreme Court permitted the EPA to regulate an effluent based on only a "reasonable" or "potential" showing of danger, rather than on the more demanding "probable" finding requested by the industrial plaintiff. In sum, "elements of the precautionary principle (are) firmly entrenched in U.S. environmental law."[11]

The criticism of the "irrationality" of EU regulatory policies toward GM foods and seeds made by American officials is thus ironic. Responding to the demands for the separation of GM and non-GM foods, US Secretary of Agriculture Dan Glickman declared that "test after rigorous scientific test has proven these products to be safe. Sound science must trump passion."[12] Yet the history of American social regulation during the 1970s and 80s is replete with examples of "passion" dominating "sound science," of which the alar ban is only the most prominent example.[13] The American automobile emission regulations enacted by Congress in 1970 reflected political jockeying between President Nixon and prospective Democratic presidential candidate Senator Edmund Muskie – with each seeking to capture the political benefits from America's sudden passion for environmentalism by proposing progressively stricter standards. The regulations approved by Congress were not based on any scientific evidence with respect to their health impacts, nor was there any effort to assess either their costs or technological feasibility.

A decade later, Congress enacted "Superfund" legislation as a response to widespread public anxiety over the health effects of toxic waste disposal sites such as Love Canal – effects which subsequent evidence revealed to have been highly exaggerated. The health benefits of this very expensive federal regulatory program have been extremely modest, yet Congress has been reluctant to reform it lest it be accused on being indifferent to the public's health. The Delaney clause, which distorted food safety standards in the US for more than a generation, was enacted in 1958 at the initiative of a single influential legislator whose wife had died of cancer.

Numerous studies of American health and safety standards have demonstrated the inconsistency of the risk assessments that underlie them.[14] Some relatively strict standards confer few or no benefits in terms of lives saved or diseases or injuries prevented, while some relatively lax standards place Americans at substantial risk of harm. This is primarily a function of the political context in which American regulatory policy-making has been embedded. Both Congress and the political appointees who head regulatory agencies have been highly sensitive to public opinion and public pressures. Consequently, the more the American public has tended to worry about a particular risk, the more strictly American policy-makers are likely to regulate it. In short, much American regulatory policy, especially between the mid 1960s through the mid 1980s, was characterized by the triumph of "passion" over "sound science."

A British social scientist observed in 1979, "Americans seem to have taken an excessively strict interpretation of risk, reducing 'reasonable risk' practically to 'zero risk.'"[15] A British journalist observed: "We saw the Americans thrashing around from one pollution scare to the next, and we were mildly amused. One moment it was cyclamates, mercury the next, then ozone, lead, cadmium – over there they seemed set on working their way in a random manner through the whole periodic table."[16] Americans observing European regulatory procedures for assessing the health or environmental impact of each GMO might well echo this observation. Their criticisms of European GMO regulation, namely that it is slow, cumbersome, highly politicized, and without an adequate scientific basis, are strikingly similar to those repeatedly made of many American consumer and environmental regulations. We now turn to a summary of American and European regulation of GMOs.

## GMO REGULATION IN THE UNITED STATES AND EUROPE

### The Regulation of Biotechnology in the United States

The regulation of agricultural products produced by biotechnology began similarly on both sides of the Atlantic, but quickly took different paths. The first steps toward regulation in the US were cautious.[17] In 1974, a group of high-level scientists called for a temporary moratorium on research involving genetic engineering, a position which was reaffirmed by a conference of biologists at Asilomar. In 1976, the National Institutes of Health introduced regulations for laboratories conducting federally-funded experiments on recombinant DNA (rDNA), the building block of genetic engineering. However, the initial support of the scientific community for strict regulatory controls was undermined by growing awareness of biotechnology's commercial potential. In addition, the growth of privately-funded experiments made the NIH regulations, which governed only government-funded work, increasingly irrelevant.

In deciding on its regulatory approach to genetically modified organisms (GMOs or GMs) the United States federal government faced two critical issues. One was whether the government already possessed sufficient legal authority to regulate biotechnology. If biotechnology was a unique and new form of agricultural technology, then new rule-making or legislation would be required. A second issue was whether regulations should govern the *process* by which genetically engineered products were produced rather than the *products* of biotechnology. The latter approach rested on the assumption that there was nothing unique in employing genetically modified seeds to produce, for example, a longer-lasting tomato, since the end product was essentially identical to that grown from conventional seeds.

Although there was little interest in this issue in Congress, the government bureaucracies responsible for addressing these issues were divided into two camps. On one side was the White House, through its Office of Science and Technology Policy (OSTP), along with the US Department of Agriculture (USDA) and the Food and Drug Agency (FDA). OSTP and the USDA were interested in promoting the economic potential of biotechnology and accordingly only wanted to regulate the products produced by biotechnology. On the other side was the EPA, which, while not calling for new legislation, insisted on the need to develop new risk assessment procedures for GMOs. This placed it on side of *process* regulation.

In 1984, the White House suggested that the Cabinet Council on Economic Affairs, rather than the EPA, be responsible for regulating biotechnology. By convening a working group under White House auspices, the White House was able to avoid public oversight since the groups's meetings

were not open to public scrutiny.[18] The Working Group, with personnel drawn from a number of different agencies, issued a *Coordinated Framework for the Regulation of Biotechnology*, which remains the key US government document on biotechnology. This framework established a biotechnology working group – the Biotechnology Science Coordinating Committee – and specified EPA, USDA, and FDA as the three primary regulatory agencies for regulating biotechnology.

Under this framework, the FDA became responsible for biotechnologically-derived medical products; the USDA for transgenic plants and the EPA for pesticidal plants and genetically engineered microbial pesticides. According to the *Coordinated Framework*, new regulations were not necessary since current laws provided adequate statutory authority for biotechnology regulation. A subsequent report from the National Research Council concluded that "the *product* of genetic modification and selection constitutes the primary basis for decisions and not the *process* by which the product was obtained," and this became the basis for regulatory American policy.[19]

The FDA and USDA actively worked to promote the introduction of GMOs. In 1997, the USDA Animal and Plant Health Inspection Service (APHIS) simplified the notification procedure for importing, releasing into the environment (as in field tests), or moving GMOs across state lines. These simplified procedures were intended to cover eighty to ninety percent of GMOs. In addition, APHIS also allowed petitions to remove from its oversight genetically engineered plants which it determined no longer presented a risk to the environment. The FLAVR SAVR™ tomato was exempted from APHIS oversight under this petition process.[20]

The FDA similarly paved the way for a simplified procedure for approving bioengineered foods in May 1994, when it determined that Calgene, Inc.'s FLAVR SAVR™ tomato was "as safe as tomatoes bred by conventional means."[21] This determination meant that subsequent applications for genetically engineered foods did not have to undergo a comprehensive scientific review simply because they are produced through the *process* of genetic engineering. This decision also affected food labeling requirements: the FDA determined that labeling was not required on the basis of the method of food production (i.e. genetic engineering), but only if the new food itself posed safety problems for consumers. To date, the FDA has imposed no labeling requirements for any genetically modified foods. While EPA did propose relatively strict regulations for the introduction of plants genetically engineered to resist pests, thanks to protests from agricultural scientists and their supporters in Congress these proposed rules were never formally adopted.[22]

In 1999, largely as a response to developments in Europe, public awareness of and opposition to genetically modified seeds and crops did emerge the United States. The May 1999 issue of *Nature* reported that Cornell University researchers had conducted laboratory tests that had shown that the use of a genetically modified Bt-corn variety could kill not only targeted pests, such as the corn borer, but also Monarch butterfly larvae. The monarch butterfly rapidly became a public symbol of the environmental hazards of GM crops. A number of American consumer organizations, such as Ralph Nader's Public Citizen, questioned the safety of genetically modified foods, while the Sierra Club announced its opposition to them on environmental grounds. A *Time* magazine poll in January 1999 reported that 81% of those surveyed supported the mandatory labeling of genetically engineered foods.[23]

The US Senate Subcommittee on Agriculture held the first Congressional hearings on GM foods and in November 1999, legislation was introduced in Congress requiring the labeling of genetically modified foods. The FDA held a series of hearings throughout the United States to reexamine whether GM foods should be considered an additive, thus requiring mandatory labeling, as well as to explore the need for further testing to ensure consumer safety. For its part, the EPA began to review its policies about whether genetically modified seeds should be subject to pest control regulations. And in January 2000, EPA directed companies marketing corn that produces Bt toxin to request that farmers voluntarily plant a buffer zone of traditional corn as a protection for monarch butterflies.[24]

In May, 2000 a panel of the National Academy of Sciences issued a report endorsing the safety of those biotech foods currently on the market and opining that the process of inserting genes from one species into another was not inherently dangerous.[25] It thus endorsed the central principle underlying the American government's existing biotech regulations, namely that genetically engineered foods pose no special risk to consumers simply because they are produced by a new process. At the same time, the report recommended that the government consider conducting long-term studies to test for harm from long-term consumption of biotech foods that may contain different and possibly more dangerous substances than those currently being marketed. It also recommended that the EPA strengthen its oversight of bio-engineered crops by regulating all crops engineered to be resistant to viruses, most of which had been exempted from oversight in the agency's 1994 proposed rules. The latter recommendation was made in response to concerns expressed by some ecologists that such plants might interbreed with wild plants, thus creating so-called superweeds. Finally, while the report was generally supportive of the role of government regulatory agencies, it did urge them to expand public access to the regulatory process.

As part of a broader initiative by the Clinton Administration to increase funding for research on the potential risks of genetically engineered crops to both consumers and the environment, the FDA subsequently announced that that it would strengthen its review of bioengineered foods and write guidelines for companies that wanted to label their products as free of genetically modified foods.[26] It also announced plans to reassure consumers about the safety of genetically modified foods by requiring developers to publish research and safety data on the internet. For its part, the U.S. Department of Agriculture stated that it would help develop standardized tests to detect tiny amounts of genetically altered corns, soybeans and other grains in order to assist food processing firms which wanted to use only foods from non-genetically modified seeds.

Responding to consumer concerns, a number of U.S. companies including Frito-Lay, McDonalds, Gerber and McCain Foods (the world's largest maker of French Fries), announced that they would not purchase any foods made with genetically altered seeds.[27] But there was little evidence of a broad consumer backlash against genetically modified foods or of increased public pressure for stricter regulations. In fact, in just two years, between 1996 and 1998, crop acreage using genetically modified seeds had increased fifteen-fold in the United States: a third of the American corn and cotton crop and more than half of the soybean crop is now grown from genetically modified seeds – representing among the most rapid adoptions of a new technology in the history of agriculture. By late 1999, it is estimated that approximately 60 percent of grocery-store food in the United States was grown from genetically modified seeds. Yet so rapid was their introduction that even as an increasing number of food products from biotechnology were being introduced into the American market beginning in the mid 1990s, consumer awareness of biotechnology remained low. Indeed as late as August 1999, only 33 percent of Americans were aware that genetically modified foods were being sold in supermarkets, while less than 3% were aware that soybeans were genetically engineered.[28]

## The European Regulation of Biotechnology

The approach to biotechnology in Europe – both at the national level and in the European Union – stands in marked contrast to that of the US. The EU first became involved in biotechnology regulation in the mid 1980s.[29] In a split similar to that which had occurred within the executive branch of the US government, the Directorate General on the Environment, Consumer Protection, and Nuclear Safety (DG XI), viewed biotechnology more skeptically than the other DGs, particularly Science, Research, and Development (DG XII). In 1985, the EU's Biotechnology Steering Committee – created only a year earlier without the participation of DG XI – established the Biotechnology Regulations Interservice Committee (BRIC), a technical committee composed of

representatives from DGs III, V, VI, XI, and XII, to serve as the main forum for developing biotechnology regulations within the European Commission.

Unlike in the US, where EPA's role had been limited, DG XI became the "chef de file," or responsible authority, within BRIC. In drafting a directive on regulating the deliberate release of GMOs into the environment it chose a process rather than product-oriented approach. Although DG XII vehemently disagreed with DG XI's more cautious regulatory approach, it was unable to change the draft directive once it was submitted to the Council of Ministers. In 1990, the European Council adopted Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms.

The Deliberate Release Directive was based on the precautionary principle. Applicants who wished to conduct field tests of GMOs were required to apply and submit an environmental risk assessment to the "competent authority" of the country where testing will occur. It further required another application to each Member State to market genetically modified products and granted each Member States the right to object to such marketing within their borders.[30] Under Article 16, any EU Member States may "provisionally restrict or prohibit" the use of sale of a product if it has justifiable reason to suspect that an approved product poses a "risk to human health or the environment."[31]

An application by a British company in 1994 to market a genetically modified canola (oilseed rape) served as one of the first tests of the EU's approach to regulation. The British Advisory Committee on Releases to the Environment – established as part of the UK's transposition of the Deliberate Release Directive into domestic law – recommended UK approval of the canola in April, and in May, the UK Department of the Environment proposed EU-wide approval. However, Denmark, Austria and Norway opposed EU-wide marketing, basing their opposition on domestically-conducted scientific research which showed problems with contamination of local natural crops of canola in their own countries. While the application was supported by a qualified-majority in February 1995,[32] because of continuing controversies within the EU over labeling of GMOs, approval of canola was delayed until mid-1997, when the company agreed to voluntarily label its product as genetically modified.[33]

Another controversy within the EU erupted over the European Commission's December 1996 decision to allow marketing of Swiss genetically engineered corn. Environmental protection and consumer groups challenged the Commission's decision as did a number of Member States. In April 1997, the European Parliament challenged the Commission's decision to permit the sale of the corn, and called on the Commission to suspend its decision until further investigation could be completed.[34] Although permission to market the corn

was eventually granted, the controversy helped prompt a major revision of EU policy concerning genetically modified foods.

The trade implications of the differences between the EU and US approaches to biotechnology became evident in 1996, when the US exported its first crop of genetically modified soybeans and corn to the EU. The 1996 soybean crop in the US was the first to contain genetically modified soybeans, which consisted of approximately two percent of the total harvest.[35] (The US ships between 25 to 40 percent of its soybeans, widely used in more than half of all processed foods, to the EU.) Although the EU had approved the import of genetically modified soybeans, the trade association EuroCommerce, along with European food retailers, demanded that the US separate genetically modified from conventional soybeans. The German division of the Unilever company canceled its order for 650,000 metric tons of soybeans unless they could be guaranteed to contain none of the genetically modified ones.[36]

Genetically engineered corn, which was approved for sale by the EU in December 1996, was exported to Europe from the US in November, although the US denied that its initial shipments of corn contained genetically modified varieties. However the arrival of GM soy and corn from the United States at the end of 1996 and the beginning of 1997 attracted considerable media attention and significantly increased public awareness and concern throughout Europe. The result was a marked change in risk assessments by regulatory authorities in a number of Member States. Directive 90/220 had not required market stage precautions, on the assumption that regulatory oversight and precaution would not longer be necessary once GM products had been approved as safe for commercial release. But in response to public protests, both France and Britain re-interpreted the Directive's scope to include the effects of agricultural practices in their risk assessment, thus extending and further strengthening the application of the precautionary principle to this technology.

These twin pressures – the applications for internal marketing of GMOs and the increasing US production and export of genetically modified crops – led to increased demands for the labeling of GM foods sold within the EU. In December 1996, the European Parliament and the Council of Ministers provisionally agreed to a compromise whereby novel foods would be labeled if there was any change in their "characteristic or food property" compared to existing food, but mixtures of genetically modified and conventional foods would not be required to be separated.[37] The Novel Food Regulation, which came into effect on May 15, 1997, did not cover foods that had already been approved, namely genetically modified soybeans and corn. However, a second Directive, adopted on September 26, required the labeling of genetically engineered soybeans and corn as "genetically modified," a more demanding

label than the earlier "may contain" labeling requirement of the Novel Foods Regulation."[38]

In May 1998 a qualified majority of the Council of Ministers adopted a proposal on the mandatory labeling of food shown by DNA and protein testing to contain genetically modified corn and soybeans. After considerable debate about the content of the label and the threshold of genetically modified material which would require labeling, in January 2000,the EU issued a relatively strict standard, requiring the labeling of food at least 1% of which was genetically modified.[39] However hardly any such foods are labeled for the simple reason that hardly any are available for sale.

**Public Attitudes in Europe**

These regulatory policies reflected an increase in public concern about the dangers of genetically modified food during the 1990s in much of Europe. Officials in the UK established a cabinet-level committee to look into the effects of "Frankenstein foods," as GMOs are commonly referred to in the British press.[40] In Switzerland, a June 1998 referendum which asked whether Swiss citizens wanted to "protect life and the environment against genetic manipulation,"[41] was defeated though by a relatively narrow margin. In Germany, where over 80% of the public expressed a negative opinion of GMOs,[42] the Social Democrats considered introducing a law to ban the use of genetically modified yeast in brewing beer.[43] In the Netherlands, participants in a demonstration organized by the Alternative Consumers' Union dressed up as a genetically engineered strawberry, the Grim Reaper, and the Devil to protest biotechnology.[44]

In January 1998, the European food industry announced plans to begin the voluntary labeling of products in order to assuage consumer fears.[45] Subsequently, Iceland, a major UK frozen food retailer, announced that it would produce a range of food products without genetically modified soy products. Its CEO, who was a member of Greenpeace, based his decision on his belief that "the public are being used as guinea pigs without their knowledge."[46] Other food processing companies, such as Haldane Foods (a subsidiary of the US-based Archer Daniel Midlands Company), announced that they would only use non-genetically modified foodstuffs in their products. J. Sainsbury and other supermarkets in the UK subsequently declared that they would not use food containing genetically modified ingredients in their store brands.[47] British retailers subsequently issued a joint standard on procuring GM-free foods.[48]

Prince Charles also joined the public opposition to bioengineered crops. Stating that genetically engineered foods take mankind into "realms that belong to God," the Prince cited concerns about long-term consequences for the

environment and human health.[49] Leading chefs in the UK announced their opposition, calling for a moratorium on GMOs. Food writers also launched a campaign against GMOs, calling genetic engineering the equivalent of "imposing a genetic experiment on the public, which could have unpredictable and irreversible averse consequences."[50] Pictures of a "Frankenstein potato" appeared on the pages of *The Economist*.[51]

Monsanto, the American based firm which is the major supplier of genetically modified seeds in the United States and thus, potentially, of genetically modified foods sold in Europe bore the brunt of public opposition to GMOs. British newspapers called Monsanto the "Frankenstein food giant" and the "biotech bully boy." To redeem its public image and that of genetically engineered food, Monsanto began a $1.6 million advertising campaign in the UK and France in 1998. In the UK, the campaign backfired: before the campaign began, 44% of British consumers surveyed had negative opinions of GMOs while after the campaign's conclusion 51% did so.[52] In France, the number of consumers who said they would not buy foods containing GMOs also rose during the campaign, though by a smaller margin. Monsanto also became the target of a number of demonstrations.[53]

## EXPLAINING TRANS-ATLANTIC DIFFERENCES

### An Overview

On June 24, 1999, the environment ministers of the EU indicated their support for a moratorium on biotechnology products, which would, among other things, limit the period of authorization for a genetically modified product.[54]. As of September 2000, the EU had not approved any new seed strains for more than two years under Directive 90/220 and the marketing of new food products under the Novel Foods Regulation has also been effectively halted. While in the spring of 2001, the EU did issue a policy framework that was intended to facilitate the approval of GMO foods and the experimental planting of GMO seeds, its impact remains unclear.

The differences between the US and the EU regulatory policies are striking. The EU had issued eighteen licenses for biotechnology products, nine of which were for genetically modified crops.[55] By contrast, the USDA has issued approvals for fifty genetically modified crops,[56] while the EPA has approved eight.[57] Nearly three-quarters of all genetically modified crops are grown in the United States, hardly any are grown in Europe. The EU and a number of Member States have enacted strict labeling requirements, while US labeling requirements are more modest, only requiring only the labels of products which differ from their non-genetically modified counterparts. While issues regarding the safety and environmental impact of GM foods and seeds

continue to surface in the United States, to date their policy impact has been remarkably modest, unlike in Europe where public opposition to GMOs has been relatively effective. [58]

Trans-Atlantic differences in public attitudes are also both persistent and substantial. Even before GM foods and seeds had become politically salient, European and American attitudes diverged. A 1995 survey of consumers reported that only 21% of American consumers regarded genetic engineering as a "serious health hazard." By contrast, the comparable figure was 85% in Sweden, 60% in Austria, 57% in Germany, 48% in the Netherlands, 39% in the United Kingdom, and 38% in France.[59] Other surveys reported similar results: between two-thirds and three-quarters of American consumers expressed their support for biotechnology and their willingness to consume food enhanced by biotechnology techniques. By contrast, 61% of Britains stated that they do not wish to eat transgenic food, while 76% of French expressed opposition to it.[60] By the late 1990s, trans-Atlantic differences in public attitudes had become more striking. While 65% of consumers in Sweden, 69% in Austria, 50% in Germany and 39 % in the United Kingdom regarded genetic modification as a serious risk in food products, only 14% of Americans did so.[61]

How can we account for such markedly different regulatory policies? We review two sets of explanations, one focusing on producer interests and the other on culture.

## Economics and Producer Interests

In light of the long-standing differences between the United States and Europe with respect to both agricultural policies and trade in agricultural products, there might well be an economic explanation for their differences in the regulation of GMOs. For the EU's failure to approve the marketing of GMOs that are considered safe in the United States represents only the latest in a series of European regulations that have restricted agricultural imports from the US. The most celebrated such case is the EU's 1989 ban on the sale of beef from cattle to whom growth hormones had been administrated, as well as on the use of these hormones within Europe. This ban, which severely reduced American beef exports to Europe, was held by a WTO dispute panel to violate the Sanitary and Phytosanitary Standards of the Uruguay Round Trade Agreement. After the EU refused to comply with the panel's judgement, the US imposed punitive tariffs on approximately $100 million worth of European agricultural exports.

But while the EU's hormone ban clearly restricted trade, it is unclear if either its intention or effect was "protectionist." The ban applied equally to both domestic and foreign beef producers, and a number of the former had previously used one or more of the restricted hormones. Indeed there was considerable

opposition to the ban in Europe from farmers – Britain, France, Ireland and Denmark opposed it for this reason – while the pressure for the ban itself came from consumer groups. Moreover, the hormone ban did not reduce imports of beef to the EU; it merely shifted their source: EU beef imports from the US and Canada declined, while those from Argentina, Brazil and Australia, where cattle growers did not rely as extensively on growth hormones, increased. In sum, while the hormone ban certainly injured American producers, it does not appear to have financially benefited European ones. It is also worth recalling that the beef hormones used by European producers prior to the ban were primarily produced by European firms, whose trade association, the European Federation of Animal Health, strongly opposed the ban.

In the case of the EU's restrictions on genetically modified foods, the decline in American agricultural exports was more substantial. The American share of European maize (corn) imports dropped from 86% in 1995 to 12% in 1999, largely because while the US has approved eleven varieties of this crop, the EU has approved only four. Losses due to blocked export opportunities for maize from the US are estimated at approximately $200 million per year. Soybean exports fell more substantially, from $2.6 billion to $1 billion, though the USDA attributed most of the decline between 1997 and 1998 to price competition from Argentinean soybeans, many of which contained GMOs.

However, as in the case of the hormone ban, it is not clear that the EU's trade restrictions have benefited European agricultural producers. Europe is essentially self-sufficient in maize and both imports and exports of this crop have been and remain modest. Moreover 75% to 80% of maize is used for animal consumption. In the case of soybeans, European production is negligible. Between 1995 and 1999 the EU produced between only 6% and 12% of domestic consumption; thus if it does not import soy from the US it must seek other sources for this important animal protein. While the voluntary reformulation of house brands by supermarkets and national labeling requirements have restricted sales of processed foods which contain soybeans or soybean products, European soybean producers have hardly been in a position to benefit from these changes since approximately 80% of US soybean imports are used for animal feed.

In sum, it does not appear that European farmers have benefited financially from restrictions on imports of crops made from GM seeds. US soybeans are a largely non-competing import and in the case of maize, European producers neither needed nor wanted import protection. Indeed to the extent that import restrictions of maize and soy from the US have raised the costs of animal feed to European farmers, they have made the latter worse off. Moreover while the beef hormone ban may have served the interests of the EC's Common Agricultural Policy by reducing Europe's beef surplus, the EU has no economic

interest in discouraging its farmers from using genetically modified seeds, especially since the latter primarily reduce costs rather than increase output. Indeed, during the early and mid 1990s, the EU as well as most European governments were quite favorable to GMOs on the grounds that they would improve the competitiveness of European agriculture.

What about the position of European farmers with respect to the planting of genetically modified seeds? Once again, there is little evidence of producer "capture" of the regulatory process. If European regulatory policies reflected the interests of Europe's agricultural producers, then France, the EU Member State most sensitive to agricultural interests, should logically have been in the forefront of opposition to GMOs.[62] Yet during the early 1990s, the government of Prime Minister Juppé was one of the strongest supporters of agricultural biotechnology within the EU. His government saw France, with its strong agri-food industry, as a potential beneficiary of this new technology. In 1996, with the support of both the seed industry association and the main farmers' union, the Agricultural Ministry approved the sale of insect-resistant (bt) maize and at the June 1997 meeting of the European Council, France was the only country to vote to authorize its cultivation. In 1998, the French government, notwithstanding protests from José Bové's radical farmers union, formally cleared Novartis bt maize as well as competing products from Agrevo and Monsanto. The same political pattern holds true in Britain, where both large agricultural and industrial interests strongly favored the use of GM seeds. To the extent that all major European farm associations have strongly supported labeling requirements, they have done so only in response to consumer opposition to food grown from GM crops. In short, were it up to European farmers, GM seeds would have found a substantial market in Europe, though perhaps less extensive than in the US.

What about the interests of biotechnology firms on both sides of the Atlantic? There is no question that public opposition to GMOs has assumed an anti-American or anti-globalization flavor. This was largely due to three factors. First, the American firm Monsanto was the first mover: the first GMO crops to arrive in Europe came from the United States, rather than being grown in Europe. In addition, Monsanto chose not to label them, thus prompting widespread antagonism on the part of European consumer groups who claimed that European consumers were being deprived of their freedom of choice. Secondly, Monsanto's purchase of a large number of seed companies as well as the rumors surrounding its introduction of a "terminator gene" created uneasiness among many European farmers: they regarded the firm's marketing of GM seeds as part of an American strategy to control European agriculture. Thirdly, the initial American exports arrived in Europe just as the United States was imposing its $100 million of punitive tariffs against European exports to the

United States, many of which were directed against European agricultural products.

Yet while Monsanto has borne the financial brunt of public opposition to GMOs in Europe, European regulatory restrictions and consumer resistance have imposed severe costs on European producers as well. In fact, historically, most innovations in GM crops have companies from companies based in Europe, such as Novartis, Rhone-Poulenc, AgrEvo/Aventis and Zeneca, all of which have experienced the same difficulties in marketing their products in Europe as Monsanto (though they have been able to market them in the US). In fact, a number of European officials, most notably British Prime Minister Tony Blair, have frequently expressed concern that restrictive European regulatory policies toward GMOs are harming the long-term development of Europe's agricultural biotechnology sector. From this perspective, the opportunity costs of EU regulatory policies to European producers have been substantial.[63]

Finally, it might be the case that European authorities are restricting or delaying the approval of GM crops developed by firms based outside the EU in order to give domestic producers additional opportunity to develop their own seeds. But there is no evidence that such a calculation has informed European policy making. In this context, it is worth recalling that approximately 40% of Swiss citizens voted in favor of a referendum to ban all GM foods and drugs, yet Switzerland is home to Novartis, a major developer of GM crops. Moreover, from the outset, European biotechnology firms, like their counterparts in the United States, supported a legal framework of GMO regulation which was as non-restrictive as possible, opposed mandatory labeling requirements and argued that GM foods should not be subject to more stringent approval procedures than other new food products.

## The Role of Culture

A number of American journalists and some Europeans have suggested that trans-Atlantic differences with respect to GMOs have cultural roots. According to the *Washington Post*, notwithstanding their different cuisines "the countries of Western Europe share a deep hostility to food fiddling of any kind. . . . to European consumers the idea of eating a hormone-injected steak or tomatoes whose genes have been reordered by science – *quelle horreur!* [64]" For northern Europeans, it is important that food be "natural" – an expectation that is much less shared by Americans who have long become accustomed to "processed" and "fast" food. As one science journalist observed, "The transatlantic difference may be that Americans are accustomed to a steady stream of novel products from a highly competitive industry, whereas Europeans tend to be more traditional about what they eat."[65]

It has also been suggested that these attitudes are related to different views of agriculture on both sides of the Atlantic: "When Europeans think of wildlife and the rural environment, they think of farmland, and for them GM technology appears to be the next step in an unwelcome intensification of agriculture. Americans, in contrast, think of the wilderness areas their national parks; they regard farmland as part of the industrial system."[66] Moreover, "European qualms about the 'contamination' of the countryside by genetically modified crops scarcely occur to Americans, whose landmass is big enough to separate its agricultural heartland from rural playgrounds."[67]

These cultural explanations have some basis in reality, but they also must be viewed skeptically. In fact, Europeans consume substantial amounts of both processed and fast foods, many of which are produced and sold by the same firms which make and market them in the United States (including McDonalds). Europeans are also exposed to a steady stream of food innovations, including frozen foods, and chocolate made with hydrogenated fats. The EU has adopted a relatively permissive policy toward the use of food additives, which are used extensively in many European countries. Opposition to GMOs has been extremely strong in Britain, yet much British cuisine can hardly be described as "natural." Likewise the irradiated foods permitted by the French government certainly stretch the definition of the term "traditional cuisine," and France has a highly innovative frozen food industry. On the other hand, not all American consumers eat at McDonalds: natural or organic foods are sold are both sides of the Atlantic, and there is no evidence that Europeans are prepared to pay a higher premium for them than Americans.

Notwithstanding the popular image of European agriculture as dominated by small, family farms using "traditional" methods of production, much of European agricultural production is highly intensive, relying, for example, on the extensive use of pesticides, other modern farming techniques and sophisticated animal husbandry, including until recently, the use of animal feed to feed farm animals. During the 1990s, the number of farms declined by between 24 and 34% in Germany, Belgium, Denmark, Portugal and France while the number of large farms increased by 86% in Germany.[68] In fact, European environmentalists have been highly critical of many European agricultural practices. For their part, Americans hardly passively accept the industrialization of agriculture: issues such as pesticide use, groundwater pollution from run-offs from farms, water depletion, and the disposal of agricultural wastes, have been politically salient in the United States. Indeed, support for a family farm "non-productivist model of agricultural production" is substantial on both sides of the Atlantic. In the United States, it served as an important theme underlying opposition to the approval of the milk hormone, BST.

While more Europeans may live in proximity to areas of agricultural production than in America, to attribute European opposition to GMOs to concern about the "contamination" of nature begs the question: why are Europeans more likely to associate, transgenic food with "menacing images of adulteration, infection and monsters" than Americans.[69] After all, pesticides also contaminate nature and threaten human health, and yet opposition to their use in Europe has been relatively muted. Or, to ask the same question differently, if European opposition to GMOs is based on the perception that genetically modifying seeds represents an "unnatural practice," then why is this perception more widely shared in Europe than the United States?

## THE NEW EUROPEAN RISK REGIME

The argument of this paper is that the differences in European and American policies toward GMOs have less to do with either economics or culture than with the emergence of a new European approach toward risk regulation. As noted above, before the mid 1980s, it was rare for a European consumer or environmental regulation, either at the national or European level, to be stricter than its American counterpart. But this is no longer the case. In some cases, most notably drug approval, European and American standards have converged, while in others, such as the regulation of asbestos or lead, European standards have "caught up" to American ones. In still other areas, such as automobile emissions, American standards remain stricter. But over the last fifteen years, the EU has enacted a number of health, safety and environmental regulations which are more restrictive than their American counterparts.

While the United States continues to permit the administration of growth hormones to cattle, the EU has banned the use of both synthetic and natural ones. Following extensive debate, the United States approved the use of a growth hormone for milk cows while the EU continues to prohibit its use. The European Commission has indefinitely extended its ban on the use of phthalate softeners in toys and child car articles, while the US has adopted a wait and see approach. Particularly over the last decade, regulatory policy-making has been more dynamic in many European countries, as well as in the EU, than in the United States. For example, EU recycling requirements are stricter than in the US, where they are governed by local rather than national laws. Europeans have made manufacturers responsible for the "life-cycle" of a wide array of goods, including cars and electronic products, and the EU is currently drafting a directive that will prohibit the use of various chemicals in small electronic products in order to promote recycling and protect landfills. Neither regulation is on the political agenda in the United States, though there have been a number of voluntary initiatives by firms. The EU has also adopted a much more

extensive array of animal protection measures than the US and is poised to adopt still more.

Over the last decade, in a number of areas the EU has replaced the leadership role of the United States in addressing global environmental problems. Through the 1980s, most major international environmental agreements—most notably CITES , the Montreal Protocol, and the International Whaling Convention—were initiated by the United States. More recently, both the Biosafety Protocol and the Basel Convention on Hazardous Wastes have been adopted by the EU, but not the US. The EU has strongly pushed for an international treaty to reduce carbon emissions, while the United States has been reluctant to support such a treaty. Not only is the issue of global warming much more salient in Europe than the United States, but a number of European countries have established programs to reduce carbon emissions, even in the absence of an international treaty. Such efforts have been still-born in the US, though there have been a number of private sector initiatives. Only with respect to placing environmental provisions in trade regimes has the US continued to play a global leadership role.

The change in the relative stringency of a number of European and American consumer and environmental standards over the last three decades can be seen in the pattern of trade disputes between the EU and the US.[70] Those disputes that revolved around regulatory policies enacted prior to the mid 1980s typically involved complaints by the EU or its Member States about the use of American regulatory standards as non-tariff barriers.. Thus the former filed complaints in the GATT about Superfund taxes, American automotive fuel economy standards, and the American tuna import ban. But for those disputes which have revolved around regulations enacted since the mid 1980s, the pattern is reversed: it is now the US which is complaining about the EU's beef hormone ban, the EU's leg-trap ban, EU eco-labeling standards and, most recently, European restrictions on the sale of crops grown with GM seeds. In short, a broad range of European consumer and environmental regulations have become stricter, both over time and vis-à-vis those of the United States.

The divergence between European and American regulations of GMOs is thus part of a much political broader phenomenon, namely the adoption of more risk-averse policies in Europe. How can we account for this development? There are three interrelated factors: the emergence of a European civic culture, the growing regulatory role of the EU, and a series of regulatory failures which have undermined public confidence in regulatory institutions and policies.

## Civic culture

Throughout most of the history of the EC, European attitudes toward environmental, health and safety regulations were geographically polarized. Germany, the Netherlands and Denmark consistently favored stricter, often most risk-averse, regulations, while Britain, France and Italy equally consistently opposed them. Much of EC environmental policy-making during the 1970s and 80s represented a struggle between the EC's three "green" Member States, where constituencies representing civic interests enjoyed considerable public support and influence, and Britain, France and Italy, where they did not. Thus the directives for automobile emissions standards or recycling requirements represented a compromise among these Member States, though over the long-run European regulatory standards have been gradually strengthened.

But strong public interest in and support for stricter health and environmental standards is no longer confined to northern Europe: over the last decade it has spread south and west. In a number of critical respects, Britain and France are no longer regulatory "laggards." During the 1990s, British public opinion and public policy became "greener" and Britain's green lobbies increasingly influential. In 1990, as part of a broader reexamination of its environmental policies, Britain formally adopted the precautionary principle as one of the "basic aims and principles supporting sustainable development."[71] Significantly, this approach toward environmental and public health risks had first been introduced in Europe in Germany, historically the EU's "greenist' Member State. The application of this principle has affected a number of British regulatory policies, including the dumping of sewer sludge in the North Sea and domestic water pollution standards. It has strained Britain's consultative regulatory style, challenging the ability of regulators to justify lax controls or regulatory delays on the grounds that they have inadequate knowledge of harm and forcing them to take preventive action in advance of conclusive scientific opinion. Britain has also played a leadership role in moving the EU toward a system of integrated pollution control, it was the strongest advocate of the EU's leg-trap ban, and public opinion has been extremely hostile toward GMOs.

While the policy changes in France have been less dramatic, the French Environment Minister under the Juppé Government, Corinne Lepage, was a leading public critic of GMOs, opposing the position of the Ministry of Agriculture. In 1997, following the election of Prime Minster Jospin, the Green Party joined the French Government for the first time. France's Green Environment Minister Dominique Voynet has been strongly critical of both the planting and marketing of GMOs in both France and in Europe and played an important role in reversing the French position on GMOs, including by refusing to give written consent to two GM food products which had been previously approved. In 1996, the French government formally adopted the precautionary

principle and three years later it established a quasi-independent food safety agency. In 2001, France became the second European nation to ban the use of animal feed (farines) to all farm animals in order to prevent further outbreaks of mad-cow disease, a decision based on the precautionary principle since there was no evidence that the farines posed a danger to either public or animal health.[72] And French public opinion has been among the most hostile to GMOs in Europe.

These developments in Great Britain and France, two of the EU's largest and more important Member States, are highly significant for European regulatory politics. Moreover they reflect a broader phenomenon. Italy, responding to public health scares, was among the first nations to pressure for the beef hormone ban and more recently the health hazards of electromagnetic transmissions have emerged as an important political issue, prompting a large-scale review of government regulatory policies. In 1999, the Green Party joined the government of Belgium for the first time. Thus the Green Party is now represented in three European governments.

Moreover, NGOs are playing an increasingly active role in politics at the European level, drawing on political support in a number of Member States. The European Bureau of Consumers Unions spearheaded the drive to ban beef hormones and European consumer groups have been active in pressuring for the labeling of GMOs. Environmental NGOs such as the Friends of the Earth and Greenpeace, as well as members of the Green Party at both the national level and within the European Parliament, have played a critical role in mobilizing public opposition to GMOs. While they are not equally influential throughout Europe, they enjoy substantial influence in a number of European countries, including in the EU's three newest Member States, Austria, Finland and Sweden.

In sum, strong public support for stricter health, safety and environmental standards is no longer confined to northern Europe. Rather in recent years, much of western Europe appears to have developed a common civic culture, one which is more risk-averse than in the past, especially with respect to issue of public health. Perhaps in part initially triggered by the 1986 Chernobyl disaster, more Europeans now appear to have become aware of their common vulnerability to the dangers of modern technology.

## The European Union

It is not coincidental that the emergence of a new European approach to social regulation during the mid 1980s corresponds to the enactment of the Single European Act (1987). The EU has played a critical role in changing the dynamics of European regulatory policies: each subsequent revision of the

Treaty of Rome has accorded civic interests greater weight in the policy process. The SEA gave environmental policy a treaty basis for the first time, specifying that preventive action should be taken whenever possible and requiring that harmonized standards take as a base "a high level of protection." The Treaty on the European Union (1993) made precaution a guiding principle of EU environmental policy: "Community policy shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken . . . "[73] The TEU also gave a treaty basis to consumer protection.

In 1995 the Consumer Policy Service of the European Commission became established as a new directorate-general, DG XXIV. (The EU had previously established an Environment Directorate, DG IX). In 2000, the unit responsible for the Novel Foods Regulation was transferred from the DG for Industry to DG XXIV. The Treaty of Amsterdam (1997) called upon the Council and the Parliament to achieve high levels of health, safety, environmental and consumer protection in promulgating single market legislation. Article 153 explicitly defined consumer policy and health protection as "rights."

EU treaties have also steadily expanded the role of European Parliament, a body in which consumer and environmental interests have been relatively influential, in shaping European legislation.[74] The SEA granted it legislative power under "cooperation" procedures, and these were expanded by the Maastricht Treaty which established "co-decision" procedures, thus giving the Parliament and the European Council co-responsibility for writing legislation. The latter's purview over environmental legislation was expanded by the Amsterdam Treaty. "Despite the limitations of co-decision, its use as the legislative procedure for environmental measures considerably strengthens the Parliament's role in the adoption of new environmental legislation."[75]

As Majone has noted, the EU is primarily a regulatory state: issuing rules is its most important vehicle for shaping public policy in Europe.[76] Notwithstanding frequent criticisms of the EU's "democratic deficit," its institutions have played an important role in strengthening the representation of civic or diffused interests. These interests have been better represented at the European level than in many Member States. As in the case of the separation of powers within the United States, the fragmentation of policy-making at the European level has expanded the opportunities for political participation by non-producer interests, when these have been backed by strong public pressures. In addition, the EU's own political and economic imperatives have contributed to strengthening European consumer and environmental standards. Since the 1970s environmental policy has been employed by the EU to legitimate its claim

to promote and represent the interests of European citizens. More recently, the EU has sought to strengthen European consumer protection standards as the lack of public confidence in the European food supply threatens the functioning of the single market.

Unlike in the United States, where the constitutional authority of the states over regulatory policies that affects interstate commerce is sharply circumscribed, Member States within the EU continue to play an important role in making consumer and environmental regulations, a role which the principle of subsidiarity has enhanced. In the case of GMOs, as in many other regulatory policy areas, many of the most restrictive regulatory polices have been issued at the national level, at times in defiance of the EU. The dynamics of regulatory policy-making at the national level have created a "race toward the top," with governments often competing both among themselves and with the EU to respond to public pressures by issuing standards that better protect public health and the environment. The continued role of the Member States in regulatory policymaking has also provided civic interests with multiple opportunities to place an issue on the European regulatory agenda, since the issuing of a regulation by any Member State invariably places it on the agenda of the other fourteen, as well as Brussels.

The dynamics of regulatory policy-making in Europe have also been affected by the success of the single market. An important consequence of the single market has been to make all European consumers increasingly dependent on, and thus vulnerable to, the regulatory policies of all fifteen Member States, as well as Brussels. It is one thing for a citizen to trust the regulatory officials of his or her own government (though as noted below such trust has in fact diminished). But it requires a considerable leap of faith for such a citizen to trust the competence of officials in each of the other fourteen member states, let alone Brussels. The EU has thus unwittingly fostered increased citizen mistrust of government regulation in Europe, which has pressured many governments, as well as in the EU itself in some cases, to adopt more rigorous regulatory standards.

In sum, the growing regulatory competence of the EU, along with the ongoing tensions between the single market and national regulations, have created a policy dynamic that has contributed to the strengthening of many regulatory standards in Europe.

## Regulatory Failures

The third factor that has contributed to the adoption of more risk-averse policies in general, and toward GMOs in particular, in Europe has been a series of regulatory failures that have undermined public confidence in the ability of

regulatory officials at both the national and EU level to adequately protect the public's health and safety.

During the latter half of the 1990s, the shortcomings of the EU's regulatory structure for food safety became highly visible. The most important food safety regulatory failure involved mad cow disease. While BSE (bovine spongiform encephalopathy) was first detected in cattle in the UK in 1982, the European Commission accepted assurances from the British Ministry of Agriculture that it posed no danger to humans. Subsequently, Britain was forced to notify other EU Member States of a potential food safety problem, especially after scientific studies showed the disease was transmittable to mice. Following a massive outbreak of BSE in 1989-1990, the European Community banned human consumption of meat from the sick cattle. While concern among the British public over health effects of eating meat of BSE-diagnosed cattle continued to grow throughout the 1990s, the British government denied the legitimacy of the public's concerns, and its position was accepted by the European Commission, which placed no restrictions on the sale of British beef.

The crisis over BSE broke in 1996 in the UK, when the British Government announced that ten cases of Creutzfeld-Jakob disease had been diagnosed in humans, and that these cases were likely related to exposure to the cattle disease of BSE. The Commission responded by issuing a global ban on the export of British beef and requiring a massive destruction of cattle in Britain, and to a lesser extent, in other Member States. While both the Commission and its scientific advisory body subsequently certified British beef as safe for human consumption, the EU's belated failure to recognize its health hazards severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based. It also significantly increased public awareness of food safety issues – at the very time when genetically modified foods were first being introduced in Europe.

It is impossible to exaggerate the significance of the regulatory failure associated with BSE on the attitude of the European public toward GM foods.[77] This was especially true in Britain, where unfavorable press coverage of agrobiotechnology increased substantially following the BSE crisis: between 1996 and 1998 the percentage of those strongly opposing genetically modified foods rose from 29 percent to 40 percent. But its ramifications were felt throughout the EU. "BSE has made people in Europe very sensitive to new technologies in the food supply industry, and very wary of scientists and government attempts to reassure them."[78] According to an official from Monsanto, "That wound [about the British Government's long insistence that there were no human health risks from mad cow disease] still has not healed. You have this low burn level of anxiety about food safety, and in the midst of all this you have a product introduction of genetically modified soybeans."[79] A

food sociologist observed, "BSE was a watershed for the food industry in this country. For the first time people realized that merely attempting to ensure a culinary end product was safe to eat was not a good enough approach. We had to look at the entire process by which food is produced."[80]

The regulatory failure associated with mad-cow disease has had important political consequences in Europe. It dramatically exposed the gap between the single market – which exposes all European consumers to products produced anywhere within the EU – and the inability of European institutions to assure the safety of the products sold within that market. At the European level it led to both the strengthening of the role of DG XXIV and the decision to create a European food safety agency, which was formally made at the Nice summit in December 2000. It has called into question the functioning of the "comitology" system, the EU's term for the structure of advisory bodies that it relies on for expert advice. The European Commission had relied on the advice of the Scientific Veterinary Committee which was chaired by a British scientist and which primarily reflected the thinking of the British Ministry of Agriculture, Fisheries and Food – advice which subsequently proved flawed.[81] While regulators from the Member States are unlikely to be replaced with those from the EU, the relationship between the EU's regulatory advisory bodies, including the yet to be established food safety agency, and the European Commission is currently in a state of flux. Officials are seeking to devise institutional arrangements that will reduce the likelihood of regulatory "capture" reoccurring.[82] The mad-cow crisis has also affected regulatory institutions and policy making at the national level, leading for example, to the creation of a consumer protection "super ministry" in Germany and the establishment of national food safety agencies in both Great Britain and France.

The mad cow crisis shows no sign of diminishing. In the fall-winter of 2000-2001, diseased cows were discovered in both France and Germany.[83] France responded by banning the use of animal feed for all farm animals, a decision with major economic consequences for French agriculture, while in Germany two cabinet ministers resigned and a member of the Green Party was appointed Minister of Agriculture. Other Member States responded by banning imports of French beef. During 2000, approximately 1,700 infected cows were discovered in continental Europe and European beef sales plummeted by 27%. The EU responded by further tightening its regulatory controls – it has issued more than 80 directives since the disease was first discovered – and the total costs to the EU and national governments are likely to reach $20 billion within the next two years. To date approximately 90 people have been afflicted, all but a few in Britain. But the long incubation period makes it impossible to predict how many more will succumb. In short, mad-cow disease represents a European economic and health crisis of historic dimensions.

Not surprisingly, mad-cow disease has shaped the way Europeans have framed the potential risks associated with GMOs. In the case of the former, an industrial food production technology which scientific experts had assured the public was safe turned out to have serious long-term averse health effects – effects which no scientists had predicted and which whose magnitude and links to particular patterns of food consumption and animal husbandry are still not fully understood. If the experts were wrong about the safety of meat produced by cows who had been feed farines, might they also be mistaken in their appraisal of the safety of food produced with yet another even more novel and unproven food production technology? Moreover, in both cases, efforts to improve agricultural productivity appeared to provide consumers with no benefits, only increased risks. Mad cow thus helped put the issue of food safety, and its links to methods of food production, at the forefront of European public consciousness. In doing so, it made public acceptance of food produced from GMOs much more problematic.

In this context it is significant that while many scientists on both sides of the Atlantic, though perhaps more in Europe, regard the most important risks associated with GMOs as environmental, and the risks to human health as ranging from minimal to non-existent, it is the latter which have dominated public discourse in Europe. This is a direct response to mad-cow disease, which has heightened European anxiety over food safety. The overwhelming public support for the labeling of foods which have been genetically modified – which has emerged as an important source of trade conflict with the United States – reflects the view of many European consumers that they have a *right* to know how the foods they are eating were produced – so that they, and not some government agency or business firm, can make appropriate purchasing decisions. And both mad-cow and the debate over GMOs have prompted a public discussion of the future of Europe's "productivist" approach to agriculture.

While mad-cow disease has reduced public confidence in government regulation at the EU level – which admittedly was not especially high to begin with – public confidence in national regulatory officials and institutions has also diminished in a number of European countries. The impact of the British Government's widely perceived regulatory failures over mad-cow require little elaboration. British policy clearly failed to address the challenges of governance presented by BSE. As one British scholar put it, "the BSE scandal represents the biggest failure in UK public policy since the 1956 Suez Crisis."[84] It also emerged on the heels of a long line of food scares in the United Kingdom, including an outbreak of e-coli in Scotland, salmonella in eggs, and listeria.

In 1999, a major public health scare emerged over dioxin contamination of food products produced in Belgium, leading to both the fall of the Belgium

Government and the removal of all food products from Belgium from food shelves throughout Europe, as well as scandal involving the safety of Coca-Cola.[85] As a senior European official noted in 2000, "the past years have seen a big dip in consumer confidence in the safety of the food supply and, as a consequence, in Member State authorities tasked with the job of overseeing the food industry. There seems to be an endless supply of (food scares.)"[86] Since those words were written, Europe has been faced with a new food safety crisis, namely the outbreak of hoof and mouth disease among sheep in several European countries.

Regulatory policies and politics in Europe have also been affected by the perceived shortcomings of regulatory policies in areas unrelated to food safety. During the 1990s, the French Government was widely criticized for responding too slowly to the public health and workplace dangers associated with use of asbestos.[87] In spite of overwhelming evidence that asbestos constituted a serious health hazard, killing approximately 2,000 people a year according to a government study, its manufacturing, importation and sale was not banned until 1996, nearly two decades after it was outlawed in the United States and after it had been banned in seven other European countries. Shortly afterward on Bastille Day, 1996, President Jacques Chirac made a dramatic announcement: all 40,000 students would be immediately transferred from France's largest university because of the serious health risks posed by asbestos contamination. Far from reassuring the public, this decision prompted citizens to wonder why the government had allowed students, staff and faculty to be exposed so long in the first place.

Another, far more consequential scandal was the apparent failure of governmental officials and doctors to protect hemophiliacs from blood contaminated with the AIDS virus.[88] This issue, which became highly visible during the early 1990s, led to the resignation and criminal indictment of three senior government officials, including the Prime Minister, and three senior medical officials were convicted of criminal negligence and fraud and sentenced to prison. Officials were accused of failing to adequately screen blood donors, delaying the approval of an American technology to test blood in order to benefit a French institute, and giving blood that they knew to be contaminated to patients. The deaths of more 300 hemophiliacs were linked to one or more of these decisions. While hemophiliacs were given contaminated blood in several countries, their rate of HIV inflection was significantly higher in France. As in the case of asbestos, the government's regulatory failure was widely attributed to its placing economic interests over public health.

"Le sang contaminé" (contaminated blood) scandal in France, like the mad-cow disease in the UK, had significant domestic repercussions. It shocked French public opinion, calling into question the public's historic high regard for

the competence of the public sector in an highly paternalistic state. It also continues to haunt French politicians, making them highly risk-averse, particularly with respect to potential threats to public health. Significantly, ministers have accepted nearly every recommendation of *L'Agence Francaise de Securité Sanitaire des Aliments*, France's recently established food safety agency, which has statutory responsibility for reviewing all government food safety policies – lest they be accused of (again) endangering public health, and possibly face legal penalties. The French decision to maintain its ban on imports of British beef, made in defiance of the EU and against the advice of the Ministry of Agriculture, was taken in response to the recommendations of the AFSSA. The haste with which the French government responded to an increase in the number of BSE cases among French cattle in November 2000 by banning the feeding of animal waste to all animals – without even waiting for a scientific assessment by AFSSA – reflects the continuing impact of the contaminated blood scandal on French health and safety policies, as in part do French policies toward GMOs.

## The Precautionary Principle

An important indication of the shift to more risk-averse regulatory policies in Europe is the increasingly important role played by the precautionary principle in risk management. Over the last decade, this principle has become increasingly influential in Europe. Since it is mentioned but not defined in the TEU, the EU has subsequently sought to articulate its role in policy-making. According to a communication from the European Commission in February 2000, its scope has broadened from environmental protection, the policy area in which it originated, to encompass human, animal, or plant health. It is intended to be invoked when "potentially dangerous effects deriving from a phenomenon, product or process have been identified, and . . .scientific evaluation does not allow the risk to be determined with sufficient certainty" because "of the insufficiency of the data or their inconclusive or imprecise nature."[89] In principle, the application of this principle is not biased toward action or delay, approval or denial. And indeed its application requires an examination of the potential benefits and costs of action as well as the enactment of regulatory policies that are proportional to the level of protection being chosen. In addition, "measures should be reviewed in the light of scientific progress and amended as necessary."

The resolution on the precautionary principle adopted by the heads of government at the December 2000 Nice summit modified the Commission's communication in two respects.[90] First, while the Commission had stressed the importance of undertaking a comprehensive scientific risk evaluation, the Nice summit adopted a more flexible approach, stating that such an evaluation may not always be possible due either to insufficient data or the urgency of the risk.

Secondly, it opened up the possibility of greater civic participation during risk assessment, stressing that public participation should be "multidisciplinary, independent and transparent," and insure that all views are heard. It went on to stress that any examination of the costs and benefits of action or inaction should take into account not only their social and environmental costs but also "public acceptability" of the final decision.

While the precautionary principle cannot be divorced from science – since "a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates" – in fact its growing popularity in Europe reflects the perception that scientific knowledge is an inadequate guide to regulatory policy.[91] It is located precisely between a logic that requires the extension of scientific knowledge and one which acknowledges the "the possible intrinsic limitations of scientific knowledge in providing the appropriate information in good time."[92] It thus simultaneously both increases public expectations of science and assumes that scientific findings cannot be trusted. In effect, it reduces the scientific threshold for regulatory policy-making. By mandating the taking of regulatory action, or inaction, in advance of scientific proof of harm, it "curtails the ability of politicians to invoke scientific uncertainty as a justification for avoiding or delaying the imposition of more stringent protection measures."[93]

The spread of the precautionary principle within Europe reflects a significant change in European regulatory policy-making. While its legal significance at both the EU and national level remains unclear, its practical effect has been to permit, even mandate, the adoption of risk-averse policies without requiring scientific risk assessments. Its serves to both promote and legitimate the politicization of regulatory decision-making, privileging the responsiveness of policymakers to public opinion. "The stringency with which the precautionary principle is applied depends upon and is also a useful barometer of deeper social and economic changes. Precautionary measures, for example, are most likely to be applied when public opinion is instinctively or knowledgeably risk-averse."[94] In a sense, the application of the precautionary principle provides a way for policy-makers to be risk-averse; it protects them as much as the public. Significantly, although French law provides that ten steps must be followed before it can be applied, ranging from an economic analysis to a comparative risk assessment, in the case of GMOs they were for the most part either poorly applied or ignored. [95]

The frequency with which the precautionary principle has been evoked in Europe among both activists and policy-makers also has an ideological dimension. It reflects not only a decline in the role of science as a guide to policy-making, but also a decrease in public confidence in the benefits of technological innovation. Frequently underlying its invocation is the assumption

that the dangers of modern technology outweigh its benefits and that to avoid future harms we need to approach innovation more cautiously. As Corrine Lepage, the former French Environment Minister put it in her book on the precautionary principle, "The precautionary principle precisely responds to the need for prudence when faced with the consequences of technological progress, whose repercussions are exponential and unknown."[96] For many environmentalists, one of its important attractions is that it enables regulatory decisions to be made in the absence of evidence regarding a casual relationship between the regulatory policy being advocated and the harm it is intended to avoid.

Yet somewhat paradoxically, European regulatory administration is also becoming more scientifically based. At both the national and the EU level, there is increased recognition of the need to strengthen the capacity of government agencies to conduct risk assessments and improve the quality of scientific information available to decision-makers. An important factor underlying this development is an increase in judicial review of regulatory decisions at both the European and international levels. Just as American regulatory agencies strengthened their scientific expertise in order to defend their decisions in federal court from challenges by both public interest groups and business, so has the need of both national and European authorities to defend their decisions before the European Court of Justice and World Trade Organization dispute panels prompted them to engage in more more rigorous scientific risk assessments. While in America such judicial scrutiny primarily took place under the Administrative Procedures Act, within the EU the ECJ has the responsibility for deciding if a particular national regulation that restricts trade is justified under Article 30, which permits import restrictions to be justified on the grounds of "the protection of health and life of humans, animals or plants."[97]

## CONCLUSION

In a number of important respects, contemporary European regulatory politics resemble those of the United States from the late 1960s through the mid 1980s. During this period, an influential segment of American elite and public opinion became more risk-averse, often focusing on the dangers of new technologies rather than their potential benefits. Indeed, there is a striking parallel between the debate in America during the early 1970s over public funding of a supersonic transport and European views on GMOs: in both cases, a significant segment of the public saw no public benefits associated with the proposed new technology, only increased risks. The significant expansion and increased political influence of public interest lobbies in the United States during the 1970s parallels the growth of NGOs and the Green Party in Europe during the 1990s. The expanded the regulatory role of the American federal government is the counterpart of the increased regulatory competence of the EU. Both

developments provided increased opportunities for the representation of civic interests and led to a wide range of relatively stringent regulatory standards. Indeed, the evolving constitutional structure of the EU – with its separation of powers and federal division of responsibilities – resembles that of the United States more than any European country, with the exception of Germany.

Finally, the United States, like Europe, experienced a decline in public confidence in government regulation due to the perception that it was ineffective: Rachael Carson's *Silent Spring*, Ralph Nader's *Unsafe at Any Speed*, Love Canal and the Exxon Valdez oil spill were the American counterparts to mad-cow disease, dioxin in the food supply, and contaminated blood. And just as the United States created a new set of regulatory institutions and administrative mechanisms to improve public accountability, so is Europe in the midst of transforming its regulatory structures, though at this point it is unclear in what ways or to what extent they will resemble those of the United States.

As noted at the outset of this paper, the precautionary principle, though never an explicit component of American law, also underlay much consumer and environmental policy-making in the United States from the mid 1960s through the mid 1980s. In America it was also applied selectively; just as in Europe, focusing on the prevention or those harms or dangers about which the public was most worried. In the case of the United States, these primarily were associated with the role of chemicals as potential carcinogens. In Europe, it has been applied in the cases of mad-cow disease and GMOs, both of which have in common the impact of agricultural production on public health.

Indeed, there is a striking parallel between these two policy areas. Because Americans have been more concerned about the risk of contracting cancer than Europeans, the United States established a separate set of regulatory procedures for handling potential carcinogens. They were treated differently, and more strictly, than products or processes which posed dangers other than cancer. By contrast, no European regulation treats potential carcinogens any more differently than any other public health hazard. In the case of GMOs, the pattern is precisely the opposite: US law treats the environmental and health hazards from GMOs no differently than any other food production technology. Europe, by contrast, has established a distinctive, and more rigorous, set of regulatory requirements for GMOs.

Thus the parallels between America in the 1970s and Europe in the 1990s have not produced policy convergence. On the contrary, European and American regulatory policies are now as divergent as they were three decades ago. What has changed is the direction of this divergence. In a number of areas, Europe has become more risk-averse, America somewhat less so. And at the

same time the health, safety and environmental risks which worried Americans are not the same as those which now preoccupy Europeans.

But this in turn raises an additional question: why have some American regulatory policies, including those governing GMOs, become less risk-averse than in the past? While a full discussion of this issue is beyond the scope of this paper, a few points can be noted. First, unlike in Europe, the political saliency of consumer and environmental policies in the United States has declined over the last fifteen years. Their appearance on the American political agenda has become sporadic rather than sustained. Secondly, unlike in Europe, where the political strength of civic interests has increased, in America their influence has diminished. This is in large measure due to the changes in partisan politics. The presidency of Ronald Reagan between 1981 and 1988, and the Republican control of the Congress since 1994, has placed environmental and consumer NGOs on the defensive. Their political energies focused on maintaining the status quo i.e. preventing the roll-back of previously enacted laws and regulations. While this effort proved relatively successful – few health, safety or environmental regulations enacted during the 1970s were weakened – it also meant that they were unable to expand the regulatory agenda. Thus while many regulatory policies in Europe have become more stringent over the last decade – including those regulating GMOs – American regulatory policies have been relatively stable.

Finally, in recent years, the United States has not experienced any regulatory failures comparable to those in Europe. There have been periodic consumer safety and environmental scares, but they have been relatively minor and their political impact has been short-lived. While the EU has struggled to put into place a regulatory structure capable of adequately protecting the safety of food produced in fifteen Member States, each with their own regulatory institutions, and each Member State is attempting to upgrade its own regulatory institutions, the United States has in place a relatively well-established set of national regulatory bodies which appear to function reasonably well. In a sense, while the American regulatory structure underwent its baptism of fire, Europe's is only beginning to address the challenge of balancing scientific risk assessment with public confidence. Significantly, while 90 percent of Americans believe the USDA's statements on biotechnology, only 12% of Europeans trust their national regulators. [98] Once suspects that had this question been asked two decades ago, the numbers might well have been reversed.

## ENDNOTES

[1] This paper draws in part on an unpublished comparative study of GMO regulation co-authored with Daihanna Lynch. The author would like to express his appreciation to INSEAD for its support of his field research in Europe and to the EUI for sponsoring the seminar at which these ideas were first presented.

[2] See, Kurk Eichenwald, Gina Kolata and Melody Peterson, "Biotechnology Food: From the Lab to a Debacle," *New York Times* January 25, 2001. According to this article, "the control this nascent industry exerted over its own regulatory destiny . . . was astonishing."

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[5] See, for example, Kathryn Harrison and George Hoberg, *Risk Science and Politics* Montreal: McGill-Queen's University Press, 1994, chapter 4.

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[8] Cameron, p. 251.

[9] Ibid.

[10] Quoted in Vogel, *Trading Up*, p. 182. Emphasis added.

[11] John Applegate, "The Precuationary Preference: An American Perspective on the Precautionary Principle," *Human and Ecological Risk Assessment* Vol. 6, no. 2, 2000, p. 438, 439.

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[17] This discussion draws on Martine Kraus, "Technology and Legal Systems: A Comparative Study of the Development and Regulation of Biotechnology in Germany and the United States" (UC-Berkeley, 1996)., Sheila Jasanoff, "Product, Process, or Program: Three Cultures and the Regulation of Biotechnology," in *Resistance to New Technology: Nuclear Power, Information Technology, and Biotechnology*, ed. Martin Bauer (Cambridge: Cambridge

University Press, 1995)., and Robert Bud, "In the Engine of Industry: Regulators of Biotechnology, 1970-86," in Bauer, ed.

[18] The Cabinet Council Working Group, established in April 1984 under the White House Cabinet Council on Natural Resources and the Environment. The working group was interagency, and chaired by White House officials rather than agency officials. See Martine Kraus, "Technology and Legal Systems: A Comparative Study of the Development and Regulation of Biotechnology in Germany and the United States" (UC-Berkeley, 1996)., pp. 49-64.

[19] National Research Council, *Field Testing Genetically Modified Organisms: Framework for Decisions* (Washington, DC: National Academy Press, 1989), cited in Jasanoff, "Product, Process, or Program."

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[21] Biotechnology of Food, FDA Backgrounder, May 18, 1994, cited in Beach, "No 'Killer Tomatoes'…"

[22] Beach, "No 'Killer Tomatoes'..."

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[82] See the other contributions in ibid.

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